

**FACTORS CONTRIBUTING TO INJECTION-RELATED
IATROGENIC EVENTS AMONG PRESCHOOL- AND SCHOOL-AGED
CHILDREN IN THE YALIMBONGO RURAL HEALTH ZONE,
TSHOPO PROVINCE, DEMOCRATIC REPUBLIC OF THE CONGO: A
MIXED-METHODS ANALYTICAL STUDY**

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ABSTRACT

Injection-related iatrogenic events represent a major patient safety challenge, particularly in rural settings where organizational constraints and shortages of medical supplies contribute to preventable complications in children. The objective of this study was to identify the factors associated with injection-related iatrogenic events among preschool- and school-aged children in the rural Health Zone of Yalimbongo, Democratic Republic of the Congo (DRC).

A sequential explanatory mixed-methods study was conducted in five healthcare facilities involving 75 children selected through stratified sampling. Quantitative and qualitative data were analyzed using SPSS version 29, Stata version 18, and thematic analysis.

The main findings showed that post-injection abscesses were the most frequent complications (40.0%). After adjustment, sterile equipment availability was the only independent protective factor (adjusted OR = 0.19; 95% CI: 0.06–0.59; $p = 0.004$), reducing the risk of adverse outcomes by 81%. In conclusion, strengthening the supply of sterile equipment, infection prevention measures, and clinical supervision appears essential for sustainably improving injection safety in rural settings.

Keywords: injection-related iatrogenesis - injection safety - patient safety – child - rural setting - Democratic Republic of the Congo.

1.0 INTRODUCTION

Injectal iatrogenies are a major component of adverse events associated with care and are an essential indicator of the quality and safety of clinical practices (Donabedian, 1988; Reason, 2000).

According to the World Health Organization (WHO), more than one in ten patients experience an adverse event during their care, nearly 50% of which could be prevented through the application of evidence-based practices. Each year, these events are responsible for more than 3 million deaths, with low- and middle-income countries bearing almost two-thirds of this burden (World Health Organization [WHO], 2024).

Injecting remains one of the most common medical procedures, with approximately 16 billion injections administered annually worldwide, nearly 90% of which are therapeutic. Unsafe injecting practices are still associated with approximately 1.67 million new hepatitis B virus infections, 315,000 hepatitis C virus infections and 33,800 HIV infections each year (WHO, 2026).

In the Americas and Europe, surveillance systems have helped to reduce their frequency, but medication errors, healthcare-associated infections, and complications related to invasive procedures persist, particularly in pediatrics and specialized care units (Pan American Health Organization, 2023; CDC, 2024; European Centre for Disease Prevention and Control, 2023). In Asia and sub-Saharan Africa, infrastructure inadequacies, difficulties in the supply of sterile equipment, inequalities in access to care, and human resource constraints promote the maintenance of risky injection practices. Post-injection infectious complications, such as abscesses, cellulitis, tissue necrosis, and nerve damage, remain frequently reported (Tagny et al., 2019; WHO, 2025, 2026).

In the Democratic Republic of Congo, injections are widely used in the management of severe paediatric conditions. However, the application of national standards for injection safety remains uneven due to disruptions in the supply of sterile equipment, limited access to continuing education, and insufficient supervision of providers (Ministry of Public Health, Hygiene and Social Security [MSPHPS], 2023, 2024).

In Tshopo province, constraints related to the vastness of the territory, the isolation of rural communities, poor health coverage, and logistical difficulties compromise the availability of medicines, medical devices, and sterile equipment, thus increasing the risk of avoidable complications, especially among children receiving injectable treatments (Ministry of Public Health, Hygiene and Social Welfare, 2024). Although Kisangani concentrates the main referral structures and health coordination activities, regional research focuses mainly on infectious diseases, maternal health, and nutrition, leaving little data on pediatric injectable iatrogenic.

These constraints are particularly pronounced in rural areas, particularly in the Yalimbongo Rural Health Zone, where isolation, logistical difficulties and low availability of medical inputs can compromise the quality of care. To our knowledge, no published analytical studies have explored the factors promoting injectal iatrogenia in children in this area. The present study therefore aims to identify the individual, occupational, organizational and structural factors associated with injectal iatrogenia in older children of school and preschool age in order to generate evidence that can guide prevention interventions and strengthen the safety of paediatric care.

1.1 Research question

To what extent are individual, professional, organizational and structural factors associated with the occurrence of injectal iatrogenia in preschool and school-age children treated in health facilities in the Yalimbongo Rural Health Zone, Tshopo Province, Democratic Republic of Congo?

1.2 Research hypothesis

It is hypothesized that injectal iatrogenia in children is significantly associated with the organizational conditions of health facilities, including the availability of sterile equipment, compliance with injection protocols, provider training, infection prevention and control practices, as well as supervision and quality assurance mechanisms.

1.3 General objective

To identify factors associated with injectal iatrogenies in preschool and school-aged children in the Yalimbongo Rural Health Zone, Tshopo Province, Democratic Republic of Congo.

1.4 Specific objectives

- i. To describe the sociodemographic and clinical characteristics of children who have experienced injectal iatrogenies.
- ii. To determine the frequency and main forms of injectal iatrogenicity observed in the health facilities studied.
- iii. To identify the individual, occupational, organizational, and structural factors associated with post-injection complications.
- iv. To assess the influence of available resources, professional practices and supervision mechanisms on the occurrence of injectal iatrogenic.

2.0 METHODOLOGY

2.1 Type and design of the study

The study adopted a sequential explanatory mixed-methods design combining a descriptive and analytical quantitative component, followed by a qualitative component intended to delve deeper into the organizational and contextual factors associated with injectal iatrogenies (Medical Research Council, 2021; Peters et al., 2013).

The study took place from April to June 2026. This period included site preparation, quantitative and qualitative data collection, verification of questionnaires, data entry, statistical processing and analysis of results.

Field of study

This study is part of the field of public health, more specifically in the field of patient safety and quality of health care. It is also an epidemiological study, in that it aims to identify and analyze the factors that promote injection-related iatrogenies in preschool and school-aged children. By focusing on care practices in the Yalimbongo Rural Health Zone, this research contributes to the understanding of the risks associated with injecting procedures and to the

generation of evidence that can guide interventions to strengthen the safety of care, prevent adverse events related to injections and improve the quality of care for children in the Democratic Republic of Congo.

2.2 Environment

This study was conducted from April to June 2026 in the Yalimbongo Rural Health Zone (Tshopo Province, Democratic Republic of Congo), composed of a General Reference Hospital and several primary care structures (MSPHPS, 2024).

2.3 Population and selection criteria

Population

The study population included older children of school and preschool age who received at least one injection, their parents or guardians, and providers involved in the administration of the injections.

Eligibility criteria

Inclusion criteria

Children

Included:

- Preschool and school-age children;
- Having received an injection;
- Whose medical record is usable;
- Whose parents have given their consent.

Service providers

- Working in the selected structures;
- Involved in administering the injections.

Exclusion criteria

The following will be excluded:

- Incomplete files;
- Refusals to participate;
- Participants who were absent from the survey.

II.4. Sampling and sample size

The sample size for the quantitative study was determined according to Schwartz's formula:

$$n = \frac{{Z^2 \times p \times (1-p)}}{{d^2}}$$

Where:

$$Z = 1.96;$$

p = estimated prevalence;

$$q = 1-p;$$

d = desired accuracy.

After correction for non-response of 10%, the minimum calculated size will be increased to ensure sufficient statistical power.

For the analytical study:

Case: children with injectal iatrogenics;

Controls: children without complications.

For the qualitative study:

Sampling will be continued until the information is theoretically saturated.

Thus, the quantitative component included 75 children, selected by proportional stratified sampling, while the participants of the qualitative component were recruited by purposive sampling until the data were saturated.

Quantitative data were collected using a structured questionnaire, a medical records extraction sheet, an observation grid and a desk audit. Qualitative data came from semi-structured interviews with providers and health facility managers. The instruments were pre-tested for clarity, relevance and feasibility.

2.5 Statistical analysis

Quantitative analyses were performed with IBM SPSS Statistics 29 and Stata 18. They included descriptive statistics, Pearson, Fisher, and Student χ^2 tests, and bivariate and multivariate logistic regressions. The results are presented as Odds Ratios (ORs) and Adjusted Odds Ratios (ORa) with their 95% confidence intervals (CIs), using a significance level of $p < 0.05$. Qualitative data were subjected to inductive thematic analysis with triangulation of sources.

2.6 Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki (World Medical Association, 2013), after obtaining administrative authorizations and informed consent from the participants.

RESULTS

Table 1: General characteristics of participants and exposure to injections (N = 75)

Variable	Mean $\pm$ Standard Deviation	Median	Min–Max	95% CI
Age of children, years	5.28 $\pm$ 3.17	5,0	1–14	4,56–6,00
Weight, kg	19.45 $\pm$ 6.86	18,8	9,2–38,2	17,90–21,00
Number of injections	7.52 $\pm$ 3.81	7,0	1–14	6,66–8,38
Safety Score, 0–8	4,37 $\pm$ 1,12	4,0	2–7	4,12–4,63
Age of Recipients, Years	40,29 $\pm$ 9,88	40,0	24–57	38,06–42,53
Professional seniority, years	12,59 $\pm$ 7,46	11,0	1–25	10,90–14,28

The children were relatively young and had received an average of 7.52 injections. The mean safety score of 4.37 out of 8 indicated intermediate compliance with recommended practices.

Table 2: Distribution of participants by health facility and provider function

Variable	Category	n	%
Health facility	HGR de Yalimbongo	35	46,7
	CS de Bolama	14	18,7
	Kwelo's CS	11	14,7
	CS of Mombongo	8	10,7
	Licensed Health Position	7	9,3
Function of the service provider	Nurse	53	70,7
	Caregiver	13	17,3
	Doctor	5	6,7
	Health Technician	4	5,3

Nearly half of the children came from the Yalimbongo HGR. Nurses administered 70.7% of the injections, confirming their central role in pediatric injectable care.

Table 3: Distribution of the types of injectal iatrogenies observed

Type of complication	N	%
Post-injection abscess	30	40,0
Cellulite	13	17,3
Tissue necrosis	12	16,0

Type of complication	N	%
Systemic infection	8	10,7
Allergic reaction	6	8,0
Sepsis	4	5,3
Paralysie post-injection	2	2,7

Complications were mainly infectious. Abscesses accounted for 40.0% of cases, followed by cellulitis and tissue necrosis.

Table 4: Key results of bivariate and multivariate analyses

Factor	Bivariate result	NOW	95% CI	p
Age < 5 years old	p = 0,265	1,54	0,52–4,55	0,440
≥ 8 injections	p = 0,544	0,63	0,20–1,97	0,430
Intravenous	p = 0,599	1,51	0,52–4,41	0,450
Provider Training	p = 0,898	0,84	0,22–3,27	0,800
Sterile material available	p = 0,004	0,19	0,06–0,59	0,004
Protocol available	p = 0,239	1,58	0,52–4,80	0,420
Regular supervision	p = 0,644	0,87	0,28–2,70	0,810
High observed risk	—	0,43	0,12–1,63	0,220

In bivariate analysis, the unavailability of sterile material was associated with a higher proportion of adverse outcomes, 56.1% compared to 23.5% in properly equipped facilities. After adjustment, the availability of sterile material remained the only independent protective factor, reducing the probability of an adverse outcome by approximately 81%.

Table 5: Themes, sub-themes and categories from the qualitative analysis

Theme	Sub-themes	Main categories	Representative verbatim
Resource constraints	Insufficient sterile equipment; supply difficulties	Ruptures of syringes, needles, gloves and consumables	"Sometimes we run out of sterile equipment for several days, which makes it difficult to take care of the children safely."
Professional practices	Variable compliance with protocols; workload; insufficient training	Inconsistent application of procedures, overload, poor access to recycling	"When there are a lot of children to take care of, it becomes difficult to follow all the steps."
Organization of care	Insufficient supervision; low incident reporting; rare audits	Irregular supervision, limited documentation, lack of systematic auditing	"Complications are often managed, but rarely documented."

Parents' perceptions	Preference for injections; low knowledge of risks; trust in providers	Perception of superior efficacy, lack of knowledge of complications	"When my child gets an injection, I think he'll heal faster."
Strategies for improvement	Strengthening resources, skills and supervision	Continuous procurement, regular training, practice audits	"Regular supervision would help to quickly correct bad practices."

The thematic analysis identified five dimensions explaining the quantitative results: material constraints, variable application of protocols, organizational limitations, parental representations and improvement strategies. This component is consistent with the announced method, based on semi-structured interviews and inductive thematic analysis.

Table 6: Integration of results according to the explanatory sequential mixed design

Quantitative result	Explanatory qualitative result	Integrated interpretation
Sterile protective material: ORa = 0.19	Frequent supply disruptions and delays	Continuity of inputs is a central determinant of safety
Intermediate Safety Score: 4.37/8	Inconsistent protocol enforcement and overload	Practices are influenced by working conditions
Predominance of abscesses: 40.0%	Asepsis difficulties and insufficient consumables	Infectious complications reflect structural and procedural failures
Nurses responsible for 70.7% of injections	Need for ongoing training and supervision	Interventions must be targeted at nurses as a priority
Adverse outcomes in under-equipped structures	Rare supervision and poorly documented incidents	Resources, clinical governance and oversight need to be strengthened

4.0 DISCUSSION

The present study shows that paediatric injectal iatrogenies observed in the Yalimbongo Rural Health Zone are mainly influenced by structural and organisational factors rather than by individual patient characteristics. Complications were dominated by post-injection abscesses (40.0%), cellulitis (17.3%) and tissue necrosis (16.0%), reflecting a predominance of healthcare-associated infections. In addition, the availability of sterile equipment was the only factor independently associated with a decrease in adverse outcomes (aOR = 0.19; 95% CI: 0.06–0.59; $p = 0.004$), representing an estimated 81% reduction in the risk of complications.

These results are consistent with Donabedian's (1988) model of quality of care, according to which structural resources condition care processes and clinical outcomes. They also corroborate Reason's (2000) "defense-in-depth" model, which explains that adverse events result primarily from systemic failures. In addition, they are in line with the implementation research frameworks of Proctor et al. (2011), Damschroder et al. (2009) and Peters et al. (2013), who emphasize the importance of organizational context in the adoption of evidence-based practices. The World Health Organization's recommendations also emphasize the critical role

of the availability of sterile devices, adherence to asepsis, and infection prevention in ensuring the safety of injections (WHO, 2024, 2025).

The qualitative results reinforce these observations by identifying supply disruptions, workload overload, inconsistent application of protocols and weak supervision as the main obstacles to injection safety. The convergence of quantitative and qualitative results thus reinforces the credibility of the conclusions and suggests that improving injection safety is based on a systemic approach integrating a continuous supply of inputs, formative supervision, continuous training of providers and a system for reporting adverse events. Despite the modest sample size and the cross-sectional nature of the study, these results provide original data that can guide policies to improve the quality of paediatric care in rural contexts with limited resources.

5.0 CONCLUSION

This study highlights that paediatric injectable iatrogenies in the Yalimbongo Rural Health Zone are mainly related to organisational failures. Complications were dominated by abscesses, cellulitis and necrosis, while the availability of sterile equipment was the only independent protective factor (ORa = 0.19; 95% CI: 0.06–0.59; $p = 0.004$), reducing the risk of adverse outcomes by approximately 81%. These results highlight the need to strengthen the supply of sterile inputs, infection prevention, formative supervision and quality assurance systems to sustainably improve injection safety and the quality of paediatric care in rural contexts with limited resources.

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Conflict of Interest Declaration

The authors declare that they have no financial, institutional, or personal conflicts of interest that may have influenced the conduct of this research, the analysis of the results, or the interpretation of the data.

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