

Medication Safety Failures and the 2022 Paediatric Acute Kidney Injury Epidemic in The Gambia: A Systems-Based Analysis

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Research Article

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Abstract

Background

Medication-related harm remains a major and preventable contributor to child mortality in low- and middle-income countries (LMICs). In 2022, The Gambia experienced a fatal outbreak of pediatric acute kidney injury (AKI) linked to contaminated paracetamol and cough syrups, exposing critical weaknesses in medicine regulation, pharmacovigilance, and health system preparedness. This epidemic provides an important policy-relevant case for examining medication safety within the framework of the World Health Organization's (WHO) Global Patient Safety Action Plan (2021–2030) and the Global Medication Safety Challenge: Medication Without Harm.

Methods

A descriptive, systems-based case analysis was conducted using secondary data sources, including peer-reviewed literature, WHO medical product alerts, and national investigation reports. Established safety and human factors models the Swiss Cheese, SHELL, SHEEP, and Endsley's Situational Awareness models were applied to examine failures across the medicine lifecycle, from importation and regulation to clinical use and public health response.

Results

The analysis identified aligned failures across multiple defensive layers. Weak import regulation and absence of routine quality testing allowed contaminated paediatric medicines to enter the formal supply chain. Passive pharmacovigilance delayed recognition of early AKI clusters, while deficits in situational awareness, fragmented communication, and limited paediatric renal care capacity constrained timely response. These interacting failures transformed toxic exposure into widespread and preventable child mortality.

Conclusion

The Gambian AKI epidemic illustrates how medication safety failures can rapidly escalate into national patient safety crises when governance, surveillance, and preparedness systems are weak. Aligning national reforms with WHO patient safety strategies through strengthened regulatory oversight, active pharmacovigilance, workforce capacity building, improved situational awareness, and integration of medication safety into emergency preparedness offers a practical policy roadmap for preventing similar events and protecting children in resource-constrained settings.

Introduction

Background and Justification of the Study

Medication-related harm is a leading and largely preventable cause of morbidity and mortality worldwide, with children in low- and middle-income countries (LMICs) disproportionately affected [1]. The World Health Organization's (WHO) Global Patient Safety Action Plan (GPSAP) 2021–2030 and the Global Medication Safety Challenge: Medication Without Harm emphasize that unsafe medicines, weak pharmacovigilance, and fragile regulatory systems remain major threats to patient safety, particularly in resource-constrained health systems [2, 3].

Acute kidney injury (AKI) is a significant contributor to childhood morbidity and mortality globally, with the highest burden in sub-Saharan Africa, where infections, dehydration, sepsis, nephrotoxic medicines, and toxic exposures are common precipitating factors [4]. Outcomes are frequently worsened by delayed presentation, limited diagnostic capacity, and restricted access to renal replacement therapy[5]. Medication-related AKI therefore represents a critical intersection between clinical care and health system governance, where failures in medicine safety can rapidly translate into fatal outcomes.

In 2022, The Gambia experienced an unprecedented surge in paediatric AKI cases, many of which were rapidly progressive and fatal[6, 7]. Investigations linked the outbreak to ingestion of imported paracetamol and cough syrups contaminated with diethylene glycol (DEG) and ethylene glycol (EG) industrial solvents with well-established nephrotoxic effects [8]. Similar DEG- and EG-related poisoning events have occurred globally, including in Nigeria, Haiti, and Panama, and more recently in Uzbekistan, highlighting persistent vulnerabilities in pharmaceutical manufacturing and supply chains [9–11].

The Gambian epidemic exposed systemic weaknesses across the medicine lifecycle, including gaps in import regulation, quality assurance, pharmacovigilance, risk communication, and emergency response capacity. Medicines assumed to be safe entered the formal supply chain and were widely administered before detection and containment. These failures reflect broader challenges identified in WHO patient safety frameworks, which emphasize medication safety as a core health system function [9, 11].

Healthcare systems in LMICs operate as safety-critical systems in which latent vulnerabilities may accumulate over time. When these vulnerabilities intersect with active failures—such as contaminated medicines harm can escalate rapidly in the absence of robust surveillance and coordinated response mechanisms [12]. This provides the central justification for examining the Gambian AKI epidemic as a systems-level patient safety failure.

Objectives of the Study

The primary objective of this study is to examine the 2022 paediatric AKI epidemic in The Gambia through a systems-based and policy-oriented lens aligned with WHO's Global Patient Safety Action Plan and Medication Without Harm initiative.

Specific objectives are to:

1. Identify systemic failures across the medicine lifecycle, including regulation, pharmacovigilance, and clinical response
2. Analyse how exposure patterns, delayed recognition, and health system constraints contributed to adverse outcomes
3. Generate policy-relevant insights to strengthen medication safety and patient safety systems in LMICs

Research Questions

This study is guided by the following questions:

1. What systemic failures contributed to the emergence and progression of the AKI epidemic in The Gambia?
2. How did exposure patterns, response delays, and health system limitations influence clinical outcomes?
3. What lessons can be drawn to strengthen medication safety, pharmacovigilance, and emergency preparedness in similar settings?

Research Hypothesis

The study is based on the hypothesis that:

The 2022 paediatric AKI epidemic in The Gambia resulted from interacting failures across regulatory, pharmacovigilance, and clinical systems, which—combined with delayed situational awareness and limited preparedness—allowed contaminated medicines to cause widespread and preventable child mortality.

Definitions of Key Terms

- **Medication-related harm:** Injury or adverse outcomes resulting from the use of medicines, including errors, substandard products, or toxic exposures
- **Acute Kidney Injury (AKI):** A rapid decline in kidney function characterized by reduced urine output and/or elevated serum creatinine
- **Pharmacovigilance:** The science and activities related to detection, assessment, understanding, and prevention of adverse effects or medicine-related problems
- **Situational Awareness:** The ability to perceive, comprehend, and project health risks to support timely decision-making
- **Medication Safety:** Prevention of avoidable harm related to medication use across the medicine lifecycle

Health Determinants and Indicators Framework

The indicators examined in this study can be contextualized within key health system determinants:

- **Preventive care:**

- Medicine quality assurance (pre-market testing, import regulation)
- Pharmacovigilance systems for early detection of adverse drug reactions

- **Promotive care:**

- Health education and community awareness influencing care-seeking behavior
- Risk communication and public health messaging

- **Palliative care:**

- Clinical management of severe AKI, including supportive care and dialysis
- Symptom management for critically ill children

- **Rehabilitative care:**

- Follow-up care for AKI survivors
- Long-term renal monitoring and recovery support

This classification highlights that medication safety failures affected all levels of care, reinforcing the need for integrated system strengthening

Methodology

Study Design

This study employed a descriptive case study design using a systems-based and policy-oriented analytical approach. It examined systemic failures associated with the 2022 paediatric acute kidney injury (AKI) epidemic in The Gambia. The study was conceptual and interpretive, focusing on secondary data to generate policy-relevant insights rather than primary data collection. The analysis was guided by the World Health Organization (WHO) Global Patient Safety Action Plan (2021–2030) and the Medication Without Harm initiative, with emphasis on identifying regulatory, organizational, clinical, and human-factor determinants of medication-related harm (13–15).

Study Area

The study focused on The Gambia, a low-resource health system in West Africa, where the 2022 AKI epidemic occurred. The analysis considered national-level medicine regulatory systems, healthcare delivery structures, and pharmacovigilance mechanisms, including both urban and rural healthcare contexts.

Method of Data Collection

Data were obtained exclusively from secondary sources. These included:

- Peer-reviewed journal articles on paediatric AKI, medication safety, pharmacovigilance, and health systems
- Official reports and public documents, including WHO Medical Product Alerts and findings from the Gambian Parliamentary Select Committee inquiry(16).

Data Collection Procedure

A purposive sampling strategy was used to select relevant documents. Sources were identified through academic databases and institutional repositories, prioritizing those providing detailed epidemiological, regulatory, and clinical information on the AKI epidemic. Documents were screened for relevance, credibility, and completeness, with emphasis on capturing the full medicine lifecycle from importation and distribution to clinical use and public health response.

Study Instrument

The primary analytical instruments were four established safety and human factors models:

1. **Swiss Cheese Model** -to identify failures across multiple system defense layers(17).
2. **SHELL Model** -to assess interactions between Software, Hardware, Environment, and Liveware (18).
3. **SHEEP Model** -to analyze System, Human, Environmental, Equipment, and Process factors(19,20).
4. **Endsley's Situational Awareness Model** - to evaluate failures in risk perception, comprehension, and projection(21)

These frameworks structured the systematic examination of system vulnerabilities and failure pathways. They were selected to reflect WHO-endorsed principles of patient safety, learning systems, and health system resilience, Table 1.

Table 1

Safety model findings from the 2022 paediatric AKI epidemic in The Gambia, alignment with WHO Global Patient Safety Action Plan, and National Policy Responses

Safety Model	Key Failures Identified in the AKI Epidemic	Relevant WHO GPSAP Strategic Objectives	Policy Actions Taken by The Gambia (Medicines Control Agency & MoH)
Swiss Cheese Model	• Weak medicine import regulation • Absence of routine quality testing • Delayed detection of medicine-related harm • Limited pediatric renal treatment capacity	S01: Build resilient health systems S03: Ensure safe clinical processes S05: Strengthen patient safety surveillance	• Immediate recall and nationwide withdrawal of implicated syrups • Suspension of importation of liquid oral medicines from high-risk manufacturers • Strengthened pre-market authorization requirements for imported medicines
SHELL Model	Software: Absence of AKI protocols Hardware: Limited diagnostics and dialysis capacity Environment: Resource-constrained facilities Liveware: Overburdened healthcare workforce	S02: Strengthen safety culture and leadership S04: Protect and support health workers S06: Ensure safe use of medicines and technologies	• Revision of medicine registration and licensing procedures • Introduction of enhanced batch documentation and manufacturer verification • Clinical alerts and interim guidance issued to health facilities
SHEEP Model	System: Weak pharmacovigilance systems Human: Limited toxicity awareness Environment: Urban–rural inequities Equipment: Inadequate renal care resources Process: Fragmented referral pathways	S01: Resilient health systems S03: Safe and effective clinical processes S05: Learning systems for patient safety	• Strengthening of adverse drug reaction (ADR) reporting mechanisms • Establishment of inter-agency coordination between MCA, MoH, and customs authorities • Engagement with WHO Prequalification and Global Surveillance systems

Safety Model	Key Failures Identified in the AKI Epidemic	Relevant WHO GPSAP Strategic Objectives	Policy Actions Taken by The Gambia (Medicines Control Agency & MoH)
Situational Awareness (Endsley)	• Missed early warning signals • Poor recognition of nephrotoxic risk • Delayed escalation and public communication	S02: Leadership and teamwork S05: Early warning and surveillance S07: Patient and community engagement	• Public safety communications and media briefings on unsafe medicines • Risk communication to healthcare workers and the public • Commitment to ongoing regulatory reform and crisis preparedness

Sampling Technique

Purposive sampling was applied to ensure inclusion of high-quality, authoritative sources relevant to medication safety, AKI epidemiology, and health system response. Priority was given to sources directly addressing the Gambian epidemic and comparable medication safety events.

Data Analysis

The analysis was conducted in three stages:

1. **Event Profiling** - development of a chronological narrative of the AKI epidemic, including case emergence, medicine exposure, and response actions
2. **Model Application** -systematic mapping of findings onto the selected safety models to identify points of failure across the system
3. **Systems Synthesis** -integration of insights to identify recurring patterns, system-level weaknesses, and policy-relevant lessons aligned with WHO patient safety priorities

The findings were interpreted within a health systems and policy framework to inform recommendations for strengthening medication safety, pharmacovigilance, and emergency preparedness.

Results

Overview of key systemic failures in the gambian aki epidemic

Application of the selected safety and human factors models revealed multiple, interrelated systemic vulnerabilities underlying the 2022 paediatric acute kidney injury (AKI) epidemic in The Gambia. Epidemiological investigations documented 82 cases and 66 deaths indicating a high case fatality

burden, with strong causal association between AKI and ingestion of contaminated medicines (OR = 1.76, 95% CI: 1.60–1.92). These findings highlight how failures across regulatory, clinical, and public health systems allowed toxic exposures to translate into widespread mortality.

Exposure patterns, dose–response relationships, and temporal dynamics

Clinician observations and outbreak investigations indicate that exposure occurred primarily through orally administered paediatric liquid medications, including paracetamol and cough syrups contaminated with DEG and EG. Exposure was widespread but clustered, reflecting distribution through formal pharmaceutical supply chains, and was typically repeated over several days, rather than a single ingestion event. Young children were disproportionately affected due to both higher exposure to syrup formulations and increased physiological vulnerability.

Although precise toxicological quantification was not available, clinical patterns support a probable dose–response relationship. Children who received repeated doses were more likely to develop severe toxicity, progressing from nonspecific symptoms to anuric or oliguric AKI and multi-organ failure. The high case fatality rate among affected children suggests exposure to toxic concentrations sufficient to cause irreversible renal injury, although the absence of patient-level exposure data precluded formal dose–response modelling.

The outbreak also demonstrated critical temporal delays across the exposure–outcome pathway. Following repeated ingestion, early symptoms were nonspecific, contributing to delayed clinical suspicion. Progression to AKI occurred after several days, consistent with toxic alcohol poisoning. Initial cases were frequently misattributed to infectious causes, delaying recognition of a common toxic source. Once severe AKI developed, rapid clinical deterioration occurred, with high mortality exacerbated by limited access to paediatric dialysis and supportive care.

1. Swiss cheese model analysis

The Swiss Cheese Model demonstrated that multiple defensive layers within the medicine safety system were simultaneously breached:

- **Pre-market controls:** Absence of routine laboratory testing allowed contaminated syrups to enter the country undetected.
- **Regulatory oversight:** Limited inspection and enforcement capacity weakened control over imported medicines.
- **Pharmacovigilance:** Passive systems failed to detect early clusters of paediatric AKI.
- **Public health response:** Delays in issuing alerts and product recalls prolonged exposure.
- **Clinical capacity:** Limited diagnostic and treatment resources reduced the ability to mitigate harm.

The alignment of these failures created a pathway through which contaminated medicines were widely distributed and administered before containment measures were implemented.

2. SHELL Model analysis

The SHELL model highlighted critical mismatches between system components:

- **Software:** Incomplete or inconsistently implemented regulatory frameworks and lack of standardized AKI detection protocols.
- **Hardware:** Limited diagnostic tools and insufficient paediatric dialysis capacity.
- **Environment:** Fragmented communication and weak inter-agency coordination.
- **Liveware:** Healthcare workers operated under high workload with limited training in toxin-induced AKI.

These misalignments reduced the system's ability to detect and respond to emerging risks.

3. SHEEP Model findings for paediatric AKI

Application of the SHEEP model identified key contributors to delayed detection and management:

- **System:** Weak pharmacovigilance and absence of a coordinated national AKI response framework.
- **Human:** Limited awareness of atypical AKI presentations among frontline healthcare workers.
- **Environment:** Disparities in healthcare access delayed presentation and referral.
- **Equipment:** Inadequate dialysis and supportive care resources.
- **Process:** Inconsistent triage, referral, and case management pathways.

4. Situational Awareness Gaps

Analysis using Endsley's Situational Awareness Model revealed deficits across all levels:

- **Perception:** Early warning signs of AKI and clustering of severe cases were consistently recognized.
- **Comprehension:** The link between medicine exposure and renal injury was immediately understood by the clinicians. However, laboratory confirmatory were not available in the country
- **Projection:** The potential scale and severity of the epidemic were underestimated, delaying decisive public health action as it was thought to be bacterial cause by certain healthcare groups which added more to the confusion.

These gaps were exacerbated by limited in-country laboratory capacity and weak real-time data sharing.

Cross-Cutting Systemic Themes

Across all analytical models, five recurring themes emerged:

1. Failure of multiple safety barriers across the medicine lifecycle
2. Delays in communication, coordination, and leadership response
3. Human factor constraints, including limited training and high cognitive load
4. Weak regulatory and pharmacovigilance systems
5. Limited preparedness for medicine-related public health emergencies

Discussion

This study demonstrates that the 2022 pediatric acute kidney injury (AKI) epidemic in The Gambia was not an isolated toxicological incident but the consequence of interacting failures across multiple layers of the healthcare and pharmaceutical safety system [22, 23]. The Results show that widespread exposure to contaminated paediatric syrups containing diethylene glycol (DEG) and ethylene glycol (EG), combined with delayed recognition and limited treatment capacity, transformed a preventable hazard into a high-mortality public health crisis. The observed exposure patterns characterized by repeated ingestion through formal supply chains highlight the systemic nature of the risk, while the temporal delays in detection and response underscore critical weaknesses in surveillance and situational awareness.

Systemic failures across defensive layers (Swiss Cheese Model)

Findings from the Swiss Cheese Model analysis underscore that the AKI epidemic emerged from the simultaneous failure of several protective barriers intended to ensure medicine safety and patient protection. Pre-market defenses failed due to inadequate quality testing of imported pediatric medicines, allowing toxic products to enter the supply chain. Regulatory oversight mechanisms lacked the capacity to detect and intercept substandard products in a timely manner, while pharmacovigilance systems largely passive delayed recognition of adverse drug reaction clusters. These failures align with the observed temporal dynamics, where early nonspecific clinical presentations and delayed signal detection prolonged exposure. Once AKI developed, limited clinical treatment capacity—particularly access to paediatric dialysis further compounded mortality, similar to findings by Oliveira CL et al., 2025 [25].

These aligned failures illustrate how latent vulnerabilities within medicine regulation and healthcare delivery can remain undetected until a sentinel event exposes them. Strengthening each defensive layer independently is insufficient; instead, redundancy and interconnection between layers are essential to prevent error propagation within safety-critical healthcare systems as stated by Wiegmann et al., 2022 [17] .

Human–system misalignment (SHELL Model)

The SHELL model analysis revealed significant misalignments between policies, resources, environments, and human actors during the epidemic. Regulatory and clinical guidelines (software) for early AKI detection were incomplete or inconsistently implemented, limiting early recognition of toxin-induced disease. Health facilities lacked essential diagnostic tools and adequate dialysis capacity (hardware), constraining both detection and management of severe cases. Organizational environments were characterized by fragmented communication and weak inter-agency coordination, which contributed to delays in escalating emerging risks.

Importantly, healthcare workers (liveware) operated under high cognitive load and with limited training in toxicological AKI, which affected both clinical decision-making and reporting. These findings align with the observed exposure–outcome progression, where nonspecific early symptoms required high clinical suspicion that was difficult to maintain in resource-constrained settings. These misalignments reduced the system’s resilience and its ability to adapt to an emerging crisis.

Gaps in AKI detection and management (SHEEP Model)

The SHEEP model provided granular insight into factors contributing to delayed AKI recognition and suboptimal clinical response. At the system level, weak pharmacovigilance infrastructure and absence of coordinated AKI response protocols hindered early detection of clustered cases. Human factors particularly limited awareness of atypical AKI presentations further delayed diagnosis. Environmental disparities in healthcare access contributed to delayed presentation, especially in rural areas, reinforcing the uneven temporal dynamics observed across cases.

Equipment shortages, particularly limited availability of dialysis machines, restricted treatment options once severe AKI developed. Process failures, including inconsistent triage and referral pathways, contributed to variability in outcomes. Together, these findings reinforce that repeated exposure combined with delayed clinical recognition creates a narrow window for effective intervention, which was frequently missed in this outbreak.

Situational awareness deficits and delayed response

Application of Endsley’s Situational Awareness Model revealed critical gaps in perception, comprehension, and projection that contributed to delayed outbreak response. While individual clinicians perceived unusual clusters of paediatric AKI, these signals were not systematically aggregated across the health system. Early cases were frequently misattributed to infectious etiologies, reflecting incomplete comprehension of the underlying toxic exposure.

Projection of the outbreak’s potential scale and severity was also limited, delaying decisive regulatory and public health action. These findings are consistent with the temporal delays observed between exposure, recognition, and intervention. Limited in-country laboratory capacity further constrained timely confirmation of DEG/EG toxicity, reinforcing uncertainty and delaying coordinated response. Improving situational awareness requires structured early warning systems, real-time data sharing, and clear escalation pathways that empower frontline clinicians to raise concerns effectively [4] .

Cross-cutting themes and implications for health system resilience

Across all analytical models, several cross-cutting themes emerged: absence of effective redundancy, communication and leadership breakdowns, amplification of risk through human factors under stress, weak regulatory enforcement, and limited preparedness for toxicological emergencies. These systemic weaknesses interacted with the exposure patterns identified in the Results—particularly repeated ingestion and delayed detection—to amplify harm and increase mortality.

These findings highlight that medication safety failures are rarely attributable to a single point of breakdown. Instead, they emerge from complex interactions between regulatory systems, healthcare delivery, and human behavior. Embedding high-reliability principles such as sensitivity to early warning signals and resilience under uncertainty can strengthen preparedness for rare but high-impact events in resource-limited settings [32, 33].

Sociocultural context and care-seeking behavior

The epidemic also highlighted the role of sociocultural factors in shaping outcomes. Delayed care-seeking, influenced by reliance on traditional remedies and initial underestimation of illness severity, contributed to advanced disease at presentation. These patterns interacted with the biological progression of toxic exposure, where delays in presentation reduced the likelihood of effective intervention. Engaging communities, strengthening health education, and building trust in healthcare systems are therefore essential components of patient safety strategies [33].

Policy implications for medication safety and patient safety systems

The findings of this study reinforce that the Gambian AKI epidemic represents a sentinel medication safety failure with implications extending beyond national borders. The observed exposure patterns, delayed temporal response, and systemic failures align closely with the World Health Organization's Global Patient Safety Action Plan (2021–2030) and the Medication Without Harm initiative [34, 35].

Failures in medicine quality assurance allowed contaminated paediatric formulations to enter the supply chain, underscoring the need for stronger regulatory oversight and accountability mechanisms. Weak pharmacovigilance systems delayed detection of early warning signals, highlighting the importance of transitioning from passive to active surveillance.

Deficits in situational awareness and clinical preparedness further amplified the crisis, demonstrating the need for workforce training, standardized clinical protocols, and integration of medication safety into emergency preparedness frameworks. These reforms are essential to prevent recurrence and to protect vulnerable populations, particularly children, from avoidable harm.

The epidemic also raises broader issues of global accountability within pharmaceutical supply chains. Ensuring medicine safety in low- and middle-income countries requires coordinated international action, including stronger export controls, regulatory harmonization, and shared responsibility among manufacturers, regulators, and global health institutions [36].

Conclusion of Discussion

In conclusion, the Gambian paediatric AKI epidemic demonstrates how repeated exposure to contaminated medicines, combined with delayed detection and systemic weaknesses, can rapidly escalate into a national patient safety crisis. Aligning national reforms with WHO patient safety frameworks provides a clear pathway for strengthening medication safety systems. Sustained investment in regulatory capacity, pharmacovigilance, clinical preparedness, and community engagement is essential to prevent similar tragedies and improve health system resilience [37].

Limitations of the Study

This analysis is constrained by its exclusive reliance on secondary, aggregated data sources, which introduces potential hindsight bias and limits the precision of epidemiological interpretation. Although outbreak investigations documented 82 cases and 66 deaths, as well as a significant association between contaminated medicine exposure and AKI, the absence of access to raw patient-level datasets restricted further analysis.

Specifically, the study could not:

- Examine temporal lags between exposure, symptom onset, healthcare presentation, and outcome
- Perform advanced causal inference modelling, beyond reported associations

Additionally, reliance on retrospective reports limits the ability to fully capture real-time decision-making processes, potentially overemphasizing system failures identified after the event.

Despite these constraints, the use of established safety and human factors frameworks enabled a robust systems-level interpretation of the epidemic, complementing epidemiological findings and providing policy-relevant insights into medication safety failures in resource-limited settings

Abbreviations

WHO: World Health Organization

TRM: Team Resource Management

RBMK: Reaktor Bolshoy Moshchnosti Kanalny (High Power Channel-type Reactor)

MoH: Ministry of Health

IAEA: International Atomic Energy Agency

EG: Ethylene Glycol

DEG: Diethylene Glycol

AKI: Acute Kidney Injury

Declarations

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Lamin Makalo; Conceptualisation, Data Validation, Visualisation, Reviewing and editing

Ethical Declaration

Not Applicable

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Conflict of Interest

The authors declare no conflict of interest.

Data Availability

All data generated or analyzed during this study are included in this published article. Additional details are available from the corresponding author on reasonable request.

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