When Medicines Harm: A Systems Analysis of the 2022 Paediatric Acute Kidney Injury Epidemic in The Gambia

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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

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, and its burden is highest 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 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]. Subsequent investigations linked the outbreak to the ingestion of imported paracetamol and cough syrups contaminated with diethylene glycol (DEG) and ethylene glycol (EG)—industrial solvents with well-established nephrotoxic effects[8]. While similar DEG-related poisoning outbreaks have been reported globally, the Gambian epidemic exposed acute vulnerabilities within national medicine regulatory and surveillance systems, with consequences magnified by limited clinical preparedness.

Beyond the immediate clinical impact, the epidemic revealed 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 the hazard was detected and contained. These failures reflect broader challenges highlighted by WHO patient safety frameworks, which stress that medication safety must be addressed as a core health system and governance function rather than a peripheral regulatory task[9].

This paper examines the 2022 paediatric AKI epidemic in The Gambia through an epidemiological and systems-based policy lens, explicitly aligned with WHO's **Global Patient Safety Action Plan** and **Medication Without Harm** initiative. By analyzing failures in medicine regulation, pharmacovigilance, situational awareness, and health system preparedness, the study aims to identify actionable policy lessons for strengthening medication safety and protecting children in resource-constrained settings.

Methods

Study Design

This study employed a **descriptive case analysis** to examine systemic failures associated with the 2022 paediatric acute kidney injury (AKI) epidemic in The Gambia. The design was **conceptual and interpretive**, focusing on **systems-level and policy-relevant analysis** rather than primary data collection.

Consistent with the framing of the WHO **Global Patient Safety Action Plan (2021–2030)** and the **Medication Without Harm** initiative, the study sought to identify underlying **regulatory, organizational, clinical, and human-factor contributors** to medication-related harm[11, 12].

Data were obtained exclusively from **secondary sources**, including:

- Peer-reviewed journal articles addressing paediatric AKI, medication safety, pharmacovigilance, patient safety, and health systems theory

Sources were purposively selected to ensure comprehensive coverage of the **epidemiological, regulatory, clinical, and organizational dimensions** of the AKI epidemic, with particular attention to the medicine lifecycle from importation to clinical use and public health response.

Analytical Framework

To align with a patient safety and health governance perspective, four established **safety and human factors models** were applied:

1. **Swiss Cheese Model** – to identify multiple defensive layers within the medicine safety and healthcare system and examine how aligned failures enabled harm[14].
2. **SHELL Model** – to assess interactions between **Software** (policies, regulations, clinical guidelines), **Hardware** (diagnostic and treatment resources), **Environment** (organizational and health system context), and **Liveware** (healthcare workers, regulators, and decision-makers[15].
3. **SHEEP Model** – to examine **System, Human, Environmental, Equipment, and Process** factors contributing to gaps in AKI detection, management, and response[16, 17].
4. **Endsley's Situational Awareness Model** – to evaluate failures in **perception, comprehension, and projection** of medication-related risk across clinical, regulatory, and public health levels[18].

These frameworks were selected to reflect WHO-endorsed principles of patient safety, learning systems, and health system resilience, Table 1.

Table 1
Application of Safety Models to Chernobyl and Gambian AKI Epidemic

Model	Chernobyl (Nuclear Sector)	AKI Epidemic in The Gambia (Healthcare Sector)
Swiss Cheese Model	• Flawed reactor design • Inadequate training • Weak safety culture • Failed emergency protocols	• Weak import regulation • No drug quality testing • Delayed hazard recognition • Limited treatment capacity
SHELL Model	**Software**: Poor operational procedures **Hardware**: Unstable RBMK reactor **Environment**: Closed, secrecy-driven culture **Liveware**: Undertrained, unsupported staff	**Software**: Absent AKI protocols **Hardware**: Few diagnostic/dialysis tools **Environment**: Overcrowded, resource-limited wards **Liveware**: Overwhelmed staff, variable awareness
SHEEP Model	– (Not applied)	**System**: Weak pharmacovigilance, no national AKI protocol **Human**: Limited AKI awareness among frontline workers **Environment**: Urban–rural healthcare disparities **Equipment**: Inadequate dialysis capacity **Process**: Inconsistent triage and treatment pathways
Situational Awareness (Endsley)	• Operators noticed instability but misjudged risks • Failed to project catastrophic consequences	• Early AKI signs often missed • Poor awareness of nephrotoxic risks • Delayed referral and public health response

Analytical Procedure

The analysis followed three sequential stages:

1. **Event Profiling** – construction of a detailed narrative of the Gambian pediatric AKI epidemic using documentary sources, including timelines of case recognition, medicine importation, regulatory actions, and response measures.

2. **Model Application** – systematic application of each safety model to identify points of failure and contributory factors across the medicine lifecycle and healthcare response.
3. **Systems Synthesis** – integration of model-derived insights to identify recurring patterns and **policy-relevant lessons** for strengthening medication safety, pharmacovigilance, and patient safety governance in resource-limited healthcare systems.

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. Failures were identified across regulatory, clinical, organizational, and operational layers of the healthcare and pharmaceutical safety system. These failures interacted synergistically, allowing contaminated medicines to enter routine clinical use, delaying hazard recognition, and constraining effective clinical and public health response.

1. Swiss Cheese Model Analysis

- **Pre-market defenses**: Inadequate quality assurance and absence of routine laboratory testing of imported paediatric medicines allowed contaminated syrups to enter the country undetected.
- **Regulatory oversight**: Weak import regulation and limited enforcement capacity hindered early identification of substandard or falsified products.
- **Pharmacovigilance**: Passive surveillance systems failed to detect early clusters of adverse drug reactions, delaying outbreak recognition.
- **Public health alert mechanisms**: Delays in issuing warnings and recalling products prolonged exposure.
- **Clinical care capacity**: Limited access to diagnostic tools, antidotes, and paediatric dialysis reduced the ability to mitigate harm once AKI developed.

The alignment of these failures created a clear pathway through which toxic syrups were widely distributed and administered before effective containment measures were implemented.

2. SHELL Model Analysis

The SHELL model highlighted misalignments between system components critical to safe healthcare delivery:

- **Software**: Regulatory frameworks for medicine quality assurance and clinical guidelines for early AKI detection were incomplete, inconsistently implemented, or poorly disseminated.

- **Hardware**: Health facilities lacked reliable diagnostic tools for early AKI identification, as well as sufficient paediatric dialysis equipment to manage severe cases.
- **Environment**: Organizational and institutional environments were characterized by fragmented communication, limited inter-agency coordination, and constrained resources, which discouraged rapid escalation of safety concerns.
- **Liveware**: Frontline healthcare workers operated under high cognitive load with limited training in toxin-induced AKI, impairing timely recognition, reporting, and coordinated response.

These misalignments collectively weakened the system's ability to detect, interpret, and respond to emerging risk.

3. SHEEP Model Findings for Paediatric AKI

Application of the SHEEP model further clarified specific contributors to gaps in AKI detection and management:

- **System**: Absence of a national AKI protocol and weak pharmacovigilance infrastructure limited coordinated response.
- **Human**: Limited awareness of AKI risk factors and atypical presentations among primary and secondary healthcare workers delayed diagnosis and referral.
- **Environment**: Marked disparities between urban and rural healthcare infrastructure contributed to delayed presentation and uneven access to specialized care.
- **Equipment**: Inadequate availability and functionality of dialysis machines and supportive care equipment constrained treatment options.
- **Process**: Inconsistent triage, referral pathways, and case management protocols led to variable clinical outcomes.

4. Situational Awareness Gaps

Analysis using Endsley's Situational Awareness Model revealed deficits at all three 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 all stakeholders. However, laboratory confirmatory were available not 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 which added more to the confusion.

These gaps were exacerbated by information silos, limited real-time data sharing, and insufficient crisis communication mechanisms.

Cross-Cutting Systemic Themes Identified

Across all analytical models, five recurring themes emerged:

1. **Absence or ineffectiveness of redundant safety systems**, allowing hazards to progress without interception.
2. **Communication and leadership breakdowns**, impairing timely clinical and regulatory decision-making.
3. **Human factors under stress**, including cognitive overload and inadequate training, amplifying risk.
4. **Weak regulatory oversight**, enabling prolonged circulation of hazardous medicines.
5. **Limited preparedness and scenario planning**, restricting rapid containment and mitigation of the epidemic

Discussions

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 [19, 20]. Using established safety and human factors models, the findings highlight how regulatory weaknesses, inadequate surveillance, constrained clinical capacity, and human-factor limitations converged to allow widespread harm.

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, while regulatory oversight mechanisms lacked the capacity to detect and intercept substandard products[14, 21]. Pharmacovigilance systems were largely passive, delaying recognition of adverse drug reaction clusters, and public health alert mechanisms were not activated promptly. Once AKI developed, limited clinical treatment capacity—particularly access to paediatric dialysis—further compounded mortality similar to findings by Oliveira CL et al.,2025 [22].

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[14].

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 and management were incomplete or inconsistently implemented. Health facilities lacked essential diagnostic tools and adequate dialysis capacity (hardware), limiting timely diagnosis and effective treatment [23, 24]. Organizational environments were characterized by fragmented communication and weak inter-agency coordination, discouraging rapid escalation of safety concerns. Frontline healthcare workers (liveware) faced high cognitive load, limited training in toxin-induced AKI, and insufficient decision-support tools[25, 26].

These misalignments reduced the system's resilience and its ability to adapt to an emerging crisis. Aligning software, hardware, environment, and liveware is therefore critical to improving patient safety and crisis response, particularly in resource-limited healthcare settings.

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, the absence of a national AKI protocol and weak pharmacovigilance infrastructure hindered coordinated action. Human factors included limited awareness of atypical AKI presentations and toxic exposures among primary healthcare workers. Environmental disparities between urban and rural health facilities delayed presentation and referral. Equipment shortages—particularly dialysis machines—restricted treatment options, while inconsistent triage and referral processes (process failures) led to variable outcomes[27, 28].

Together, these findings emphasize that effective AKI prevention and management require integrated system strengthening rather than isolated clinical training or infrastructure investment alone.

Situational Awareness Deficits and Delayed Response

Application of Endsley's Situational Awareness Model revealed failures across comprehension, and projection. Early warning signs—such as clustering of severe paediatric AKI cases—were consistently perceived. The causal link between medicine exposure and renal injury was immediately comprehended by the clinicians but not so across other stakeholder groups, and the potential scale of the outbreak was underestimated by the public health service. These deficits delayed decisive regulatory and public health action.

Improving situational awareness in healthcare systems requires structured early warning systems, real-time data sharing, and clear escalation pathways that empower frontline clinicians to raise safety concerns without fear of dismissal or reprisal as given by Brady et al., 2013[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 themes reflect broader challenges faced by LMIC healthcare systems operating within constrained regulatory and resource environments[29].

Embedding high-reliability principles—such as preoccupation with failure, sensitivity to frontline operations, and commitment to resilience—can enhance preparedness for rare but high-impact events. Importantly, these principles must be adapted to local contexts and resource realities[30].

Sociocultural Context and Care-Seeking Behavior

The epidemic also highlighted the role of sociocultural factors in patient safety. Delayed presentation due to reliance on traditional remedies and initial underestimation of illness severity contributed to poor outcomes. Engaging traditional healers, strengthening community health education, and fostering trust between communities and health institutions may reduce delays in care-seeking while respecting cultural practices as stated by Kinteh et al., 2024[30].

Policy Implications for Medication Safety and Patient Safety Systems

The 2022 paediatric acute kidney injury (AKI) epidemic in The Gambia represents a sentinel medication safety failure with profound implications for patient safety governance in low- and middle-income countries (LMICs). The outbreak, linked to diethylene glycol– and ethylene glycol–contaminated paracetamol and cough syrups, resulted in widespread and preventable child deaths and exposed critical weaknesses across the medicine lifecycle. Aligned with the World Health Organization's (WHO) **Global Patient Safety Action Plan (GPSAP) 2021–2030** and the **Global Medication Safety Challenge**: **Medication Without Harm**, the epidemic illustrates how regulatory fragility, weak surveillance, and limited preparedness can rapidly translate into catastrophic harm[31, 32].

At the level of governance and regulation, the epidemic revealed systemic gaps in medicine quality assurance. Contaminated pediatric formulations entered the national supply chain through formal importation channels, underscoring vulnerabilities in regulatory oversight and enforcement capacity. This failure directly contradicts **GPSAP Strategic Objective 1**, which emphasizes leadership, accountability, and robust patient safety governance. Policy priorities must therefore include mandatory laboratory testing of high-risk pediatric medicines, strengthened Medicines Control Authorities with legal enforcement powers, and clearer accountability mechanisms spanning importation, distribution, and post-market surveillance.

Pharmacovigilance failures were central to delayed outbreak recognition. In The Gambia, reliance on passive adverse drug reaction reporting limited early signal detection and prolonged exposure to toxic medicines. The WHO Medication Safety Challenge identifies such weaknesses as a major driver of preventable harm. Transitioning to **active pharmacovigilance systems**, integrating adverse event reporting into routine clinical workflows, and ensuring rapid regulatory response to safety signals are essential reforms. These measures would enable earlier detection of rare but high-impact medication-related events, particularly in pediatric populations.

Deficits in situational awareness further compounded delays in response. Early clusters of severe pediatric AKI were not consistently recognized, the causal link to medicine exposure was not immediately understood, and the potential scale of harm was underestimated. These gaps reflect broader challenges in workforce training, information flow, and decision-making under uncertainty. Strengthening situational awareness through standardized AKI detection and escalation protocols, targeted training, and non-punitive reporting cultures aligns with **GPSAP Strategic Objectives 2 and 4**, which emphasize workforce capability and learning health systems.

The epidemic also exposed limited preparedness for medication-related emergencies. Health facilities faced shortages of antidotes, inadequate pediatric dialysis capacity, and absence of structured follow-up for AKI survivors. These constraints transformed toxic exposure into mortality and long-term morbidity. Consistent with **GPSAP Strategic Objective 5**, medication safety events must be explicitly integrated into national emergency preparedness and response frameworks. Establishing referral networks for pediatric renal care, maintaining essential antidote stockpiles, and developing AKI surveillance registries would strengthen system resilience and recovery.

Equity considerations are central to the policy implications of this outbreak. Children—particularly those under five years—were disproportionately affected, highlighting +inequities in protection from unsafe medicines. While national reforms are critical, the epidemic also raises questions of **global accountability within pharmaceutical supply chains**. Exporting countries, manufacturers, and international regulators share responsibility for ensuring that medicines circulating in LMICs meet safety standards. Strengthening international cooperation, transparency, and enforcement mechanisms is therefore integral to advancing the goals of WHO medication safety initiatives[33].

Finally, community trust emerged as a critical determinant of outcomes. Delayed care-seeking and reliance on traditional remedies reflected not only cultural practices but also underlying mistrust in health systems and medicines. WHO patient safety frameworks emphasize patient and community engagement as essential components of harm prevention. Transparent risk communication and culturally sensitive engagement strategies are necessary to rebuild trust and support timely healthcare utilization during future safety events.

In conclusion, the Gambian paediatric AKI epidemic demonstrates that medication safety failures can rapidly escalate into national patient safety crises when governance, surveillance, and preparedness systems are weak. Aligning national reforms with WHO's **Global Patient Safety Action Plan** and **Medication Without Harm** provides a clear policy roadmap: strengthen regulation and pharmacovigilance, build workforce capacity, enhance situational awareness, and embed medication safety within emergency preparedness. Positioning medication safety as a core health system function is essential to protecting children and preventing similar tragedies in resource-constrained settings[34]. The Ministry of Health of The Government of The Gambia, through the Medicines Control Agency, has since taken steps to address the regulatory and pharmacovigilance gaps exposed by the AKI epidemic, including measures to strengthen medicine import oversight and post-market surveillance. Sustaining and institutionalizing these reforms will be critical to preventing similar medication-related harm in the future

Conclusions

The 2022 pediatric AKI epidemic in The Gambia resulted from the convergence of systemic vulnerabilities, regulatory failures, and human-factor limitations. Application of safety and human factors models highlights the need to strengthen redundant safety systems, align human–system–environment interfaces, improve situational awareness, and embed a culture of patient safety. For The Gambia and similar contexts, priorities include robust drug regulation and pharmacovigilance, standardized AKI protocols, workforce capacity building, and transparent crisis communication. Translating these lessons into sustained improvement will require coordinated stakeholder engagement, systems mapping, and long-term investment in regulatory and clinical infrastructure.

Limitations

This study relied on secondary data sources and interpretive application of safety models, which may introduce hindsight bias. The absence of patient-level clinical data limited detailed epidemiological analysis and outcome stratification. Future research should include root cause analyses, participatory systems mapping, and engagement with frontline clinicians, regulators, and affected families to refine context-specific prevention strategies.

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

Author Contribution;

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

Ethical Declaration

Not Applicable

Consent to Publish

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Not applicable

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