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REVIEW ARTICLE

Diethylene Glycol Contamination in Pediatric Cough Syrups: Clinical and Public Health Perspectives

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Abstract

Background: Diethylene glycol (DEG) contamination of pediatric oral liquid pharmaceuticals continues to be a recurring and avoidable cause of mass poisoning, particularly in low- and middle-income countries. Recurring outbreaks, the most recent of which occurred in India in 2025, expose grave flaws in pharmaceutical production, excipient quality control, and regulatory supervision despite decades of awareness. Due to their physiological vulnerability and the widespread usage of cough syrups, children are disproportionately affected. **Methods:** PubMed/MEDLINE, Embase, Scopus, Google Scholar, WHO Medical Product Alerts, US FDA Safety Alerts, and national regulatory databases were employed in this PRISMA-guided review. Studies published in English between January 2010 and December 2025 that revealed DEG or ethylene glycol contamination in oral liquid pharmaceuticals of pediatric importance were taken into consideration. Data gathered included clinical indicators, outbreak characteristics, sources of contamination, mortality, and regulatory failures. The dependability of the source was assessed based on the level of documentation and laboratory confirmation. **Results:** Thirty -two of the 1,246 records found satisfied the requirements for inclusion. There were four significant epidemics that were regularly reredoses 300 paediatric deaths occurred in The Gambia (2022), Uzbekistan (2022), Indonesia (2022), and India (2025). Contamination was mostly caused by subpar or adulterated excipients such propylene glycol and glycerine. The clinical presentation was similar, proceeding from gastrointestinal symptoms to metabolic acidosis, severe renal injury, and multi-organ failure, with fatality rates ranging from 30% to 70%. Systemic issues included inadequate excipient testing, falsified certificates of analysis, insufficient regulatory enforcement, poor supply-chain traceability, and delayed recall procedures. **Conclusion:** Due to preventable errors in drug quality control and regulation, DEG contamination in paediatric syrup is a continuous global public health concern. Strengthening excipient verification, enforcing batch-wise testing, improving pharmacovigilance, and implementing robust reforms are essential to preventing further paediatric morbidity and mortality.

Keywords: Diethylene glycol, cough syrup adulteration, Paediatric nephrotoxicity, drug quality control, CDSCO reforms

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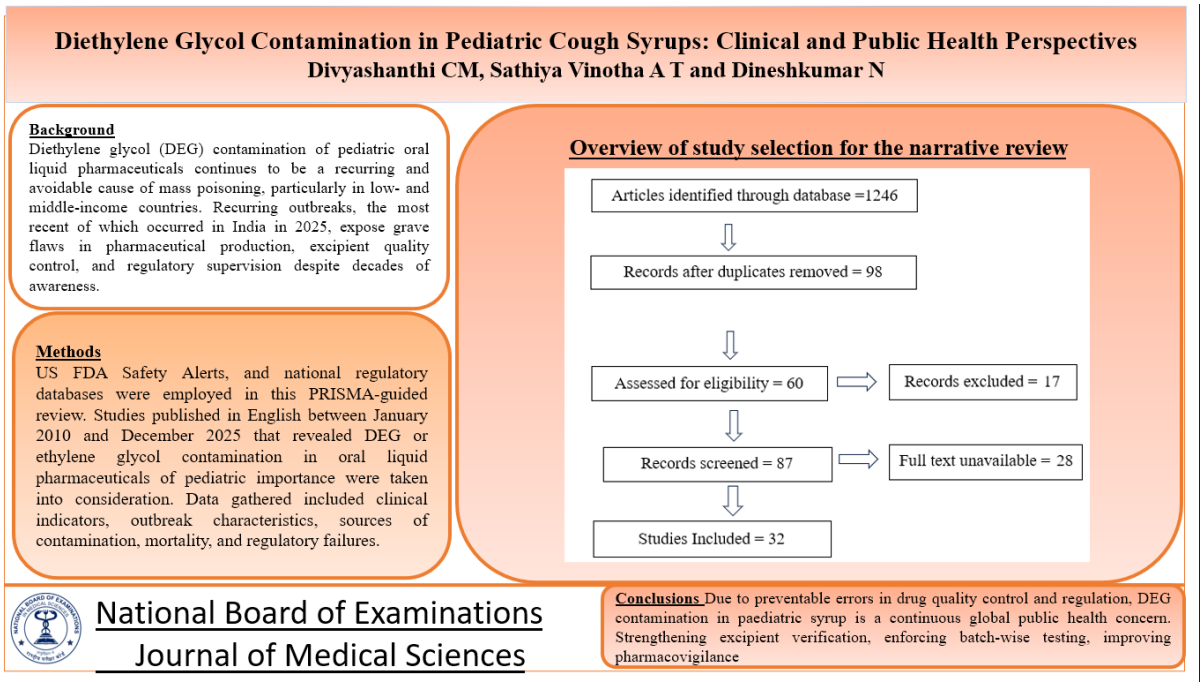
Graphical Abstract



Introduction

Some of the deadliest pediatric poisoning outbreaks in the history of world health have been caused by diethylene glycol (DEG) poisoning from tainted oral liquid medications [1,2]. DEG pollution persists despite decades of knowledge, particularly in low- and middle-income countries (LMICs) [3,4]. Due to their smaller stature, delayed diagnosis, and frequent use of cough syrups for minor ailments, children are disproportionately impacted [5].

In September and October of 2025, scores of young children in Madhya Pradesh's Chhindwara area died from a common prescription for cough treatment. After consuming Coldrif cough medication, which included diethylene glycol (DEG) at concentrations up to 500 times the allowable limits, at least 21 children under the age of five died from severe renal damage [6].

This episode demonstrates a persistent failure in drug safety, much with the 2022 Gambia tragedy in which 70 infants perished from Indian-exported syrups contaminated with DEG and ethylene glycol [7]. Since 2022, the World Health Organization (WHO) has issued numerous alerts worldwide, connecting these contaminations to over 300 juvenile fatalities in seven different countries [8,9].

These situations need for prompt observation and response because oral syrups are the most popular pediatric prescription in India because of their palatability and ease of administration. DEG, an inexpensive industrial solvent that mimics the sweetness of glycerin, is used with excipients such as propylene glycol to reduce costs [10,11]. Lethality is increased in children because to their smaller body weight and immature renal clearance; symptoms progress from vomiting to anuria and death in 24 to 48 hours [12]. This article explores the topic from the perspectives of pharmacology and pediatrics through a compilation of reports and literature (searched via PubMed, WHO databases,

and news archives for "DEG cough syrup deaths 2020–2025"). We describe the epidemiology, procedures, quality concerns, policy flaws, and measures to stop such tragedies.

International attention was sparked by the 2025 India incident, where a number of pediatric syrups were declared unsafe due to laboratory results of increased DEG concentrations. In accordance with PRISMA guidelines, this review summarizes the worldwide data, causality, and regulatory shortcomings that contribute to these recurring outbreaks. The important data on deaths from DEG-Contaminated Cough Syrup from 2020 to 2025 is shown in Table 1 [13-17].

Table 1. Key Statistics on DEG-Contaminated Cough Syrup Deaths (2020–2025)

Incident/Year	Location	Product(s)	Child Deaths	Key Findings
Jammu, India (2019–2020)	Jammu &Kashmir	Multiple syrups	≥12	DEG in excipients; underreported acute kidney injury [13]
Gambia (2022)	Gambia	Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup, Magrip N Cold Syrup (Maiden Pharma, India)	66–70	WHO-confirmed DEG/EG; bribery allegations in testing; export scandal [14,15]
Uzbekistan (2022)	Uzbekistan	Doc-1 Max (Marion Biotech, India)	65	Bribery ($33,000) to skip tests; license suspension [16]
India (2025)	Madhya Pradesh/Rajasthan	Coldrif (Sresan Pharma), Respifresh (Rednex Pharma), ReLife (Shape Pharma)	19–24	DEG 500x limit in Coldrif; 364 manufacturing violations; arrests and bans [17].
Total (WHO est., 2020–2025)	Multiple countries	Various Indian syrups	>300	Primarily <5 years; >140 export-linked since 2022.

Methods

This review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Eligibility criteria

Studies were suitable for inclusion if they described diethylene glycol (DEG) or ethylene glycol (EG) contamination in oral liquid pharmaceutical products and offered information relevant to children, including clinical aspects or outcomes. Toxicology or regulatory assessments that looked at the causes, pathways, or system-level failures connected to DEG contamination were also included, as were reports from the US FDA, the European Medicines Agency, the WHO, and national regulatory authorities. Only publications in English from January 2020 to December 2025 were evaluated. Studies describing methanol poisoning unrelated to pharmaceuticals, industrial-use DEG without connection to medicinal products, or purely animal or laboratory studies with no public health relevance were excluded.

Search strategy

A comprehensive search was conducted across PubMed/MEDLINE, Embase, Scopus, Google Scholar, and official regulatory alert systems including the WHO Medical Product Alerts, US FDA Safety Alerts and national regulatory sites from India, Indonesia, Uzbekistan and The Gambia. The keywords used in the search strategy related to DEG contamination, oral liquid medicines, paediatric poisonings were “diethylene glycol” OR “ethylene glycol” AND “cough syrup” OR “oral liquid” OR “paediatric syrup” AND “contamination” OR “adulteration” OR “toxicity” OR “poisoning” AND “children” OR “paediatric”.

A full -text review of possibly suitable studies was conducted after a preliminary screening of titles and abstracts. Any disputes were settled by consensus. Data on the country and year of the epidemic, the type of contaminated product, measured DEG levels, identified sources of contamination, clinical presentations, death figures, regulatory shortcomings, and documented outcomes were collected for each included study.

The risk of bias was evaluated based on the type of source: media accounts were only used when they were backed by credible documentation, but WHO alerts and regulatory reports were regarded as extremely reliable because of laboratory confirmation. Research was included if it: oral liquid medicinal medications have been found to include ethylene glycol (EG) or diethylene glycol (DEG).

Reports from reputable regulatory organizations, such as the US FDA, European Medicines Agency, WHO, or national drug regulatory authorities, contains information pertinent to children, such as clinical manifestations or outcomes, toxicological, epidemiological, or regulatory analyses addressing the causes, pathways, or systemic failures related to DEG contamination. Studies that reported methanol poisoning unrelated to pharmaceutical products, talked about industrial or environmental DEG exposure unrelated to pharmaceutical products, or involved animals, laboratories, or experiments with no direct bearing on public health were all disqualified.

Data Extraction

The following data were extracted from the each included study: Country and year outbreak, Type of contaminated pharmaceutical product, measured levels of diethylene glycol, Source and mechanism of contamination, Clinical manifestations and complications, Mortality data, identified regulatory or manufacturing deficiencies, Reported outcomes and public health responses.

Risk of Bias Assessment

The reliability of the source was assessed by nature of the report. Laboratory confirmation and formal documentation made WHO alerts and regulatory authority reports extremely trustworthy. Media reports were included when they are supported by reliable scientific or regulatory sources.

Results

Out of the 1,246 records, after removal of duplicates 98 were remained.60 full text papers were screened and 32 satisfied the eligibility requirements (Figure 1). These included reports from regulatory investigations, WHO medical alerts, peer – reviewed toxicological and clinical research, analysis of epidemiological outbreaks, and chemical quality evaluations of excipients.

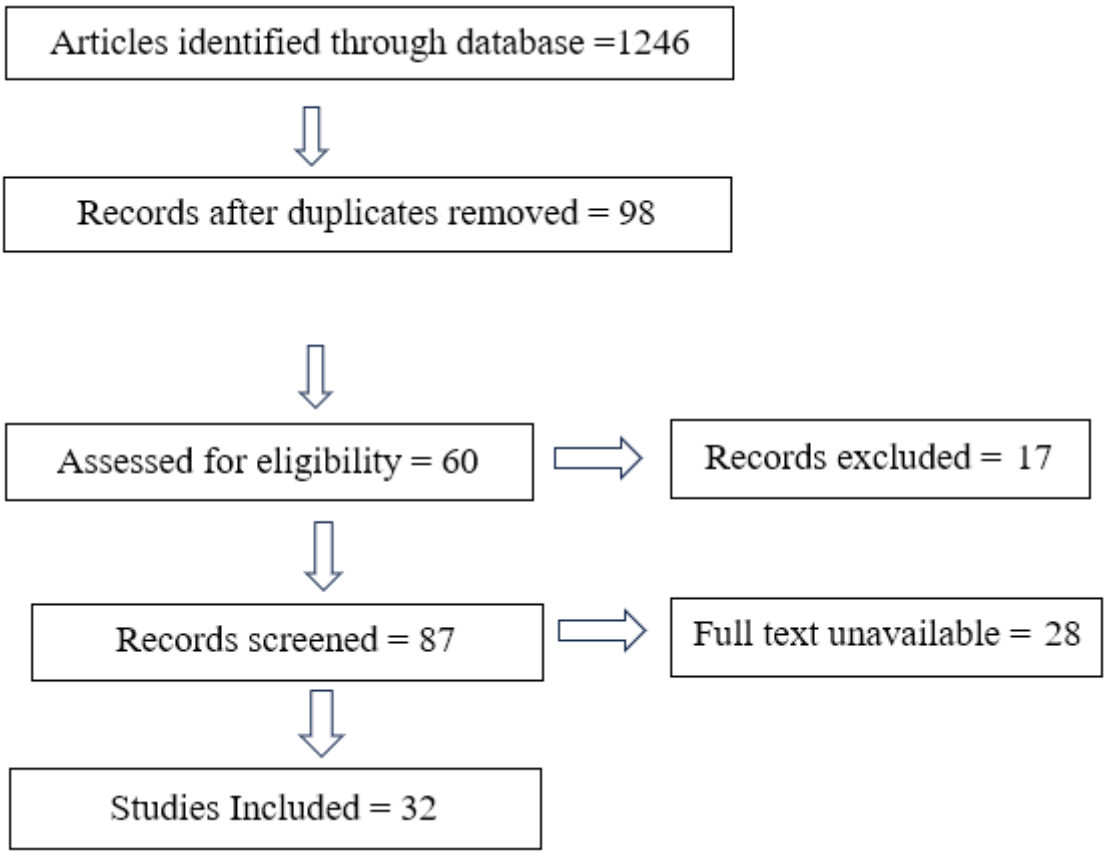


Figure 1. Overview of study selection for the narrative review

Four significant paediatric outbreaks were frequently reported in all of the analyzed sources: India (2025), Indonesia (2022), Uzbekistan (2022) and The Gambia (2022). These incidents collectively accounted for hundreds of deaths, with particularly high mortality in Indonesia and Gambia. The common feature in all outbreaks was contamination of pediatric syrups, typically cough and cold preparations, with DEG or EG. The use of industrial-grade raw ingredients or the replacement of pharmaceutical-grade excipients with less expensive alternatives were the underlying reasons, which varied slightly but were always connected to tainted glycerin or solvent-grade excipients.

Clinical presentations across outbreaks were uniform. Affected children typically presented with nonspecific symptoms such as vomiting and abdominal pain, which rapidly progressed to high-anion-gap metabolic acidosis, Kussmaul respiration and oliguria or anuria. In many cases, clinical deterioration was rapid, leading to acute kidney injury, central nervous system depression, seizures and multi-organ dysfunction. The death rates in several outbreaks, which ranged from 30% to 70%, show the potency of DEG as a renal and metabolic toxin and the challenges of early diagnosis in young populations [18,19].

By examining contamination pathways, recurrent systemic vulnerabilities were discovered. Many manufacturers failed to conduct independent testing of excipients and instead relied on inaccurate or insufficient Certificates of Analysis. Supply chains frequently lacked traceability, and many businesses violated standard Good Manufacturing Practice regulations. Inadequate staffing, few inspections, and a sluggish response to early warning signs are common signs of weak regulatory management in affected countries. Because post-marketing surveillance and recall systems were either nonexistent or poorly implemented, contaminated batches were often permitted to remain in circulation for prolonged periods of time [20,21].

Discussion

This thorough analysis shows that DEG contamination of pediatric oral liquid medications is a persistent worldwide issue linked to avoidable errors in manufacturing and regulation. Poor quality assurance practices, insufficient supply chain verification, tainted excipients, and delayed regulatory responses were common upstream causes of all the outbreaks under examination. Due to serious structural faults in pharmaceutical quality control systems worldwide, widespread poisoning continues despite long-standing WHO standards. The 2025 Indian epidemic is remarkably similar to previous crises in Indonesia, The Gambia, and Uzbekistan, suggesting that production practices and regulatory frameworks have not adequately taken into account the lessons learnt from previous calamities [22].

For a number of reasons, children are more vulnerable to DEG poisoning. Compared to adults, they have a far higher hazardous dose per kilogram due to their lower body weight. The widespread usage of pediatric syrups for common ailments raises the danger of exposure during contamination incidents. Furthermore, early signs of DEG toxicity, such lethargy and vomiting, are frequently confused with common children's diseases, delaying

detection until renal damage is more severe. Reversibility is restricted and mortality rises dramatically once metabolic acidosis or anuria develops, particularly in environments with limited access to dialysis or pediatric critical care [23].

From an epidemiological perspective, these incidents primarily affect children under five in low-resource environments where access to over-the-counter syrup and informal markets are common. 70% of 2025 instances in India are found in rural areas like Chhindwara, where self-medication for respiratory conditions is the main cause. According to WHO data, there have been over 300 deaths worldwide since 2022, with 140 of the deaths being attributed to imports from India. Post-monsoon spikes are correlated with cough season and supply chain vulnerabilities, according to trends [24].

Alcohol dehydrogenase breaks down DEG ($C_4H_{10}O_3$) pharmacologically into toxic intermediates: glycolic acid causes metabolic acidosis, while oxalic acid produces renal calcium oxalate crystals that induce acute tubular necrosis. Glomerular filtration rates in children (5–10 mL/min/1.73 m^2 at birth, maturing to adult levels by 2 years) delay clearance, reducing the lethal dose to 1-2 mL/kg as opposed to 5–10 mL/kg in adults. Case studies from the Gambia show that, despite receiving hemodialysis, children experienced gastrointestinal pain and oliguria 12–24 hours after ingestion, which resulted in unconsciousness and 30–50% mortality. At this point, pharmacovigilance is necessary: pediatricians should query formulations when evaluating a patient's history, while pharmacologists advise routine excipient testing. If nothing is done, annual underreporting could hide thousands of cases [25,26].

Quality Control Issues: From Adulteration to Market Entry

Cost – driven alternatives are the main source of adulteration: DEG enters the market from unregulated vendors and costs around a tenth of pharmaceutical -grade propylene glycol. In the 2025 Coldrif case, the Sresan Pharma Facility broke 364 regulations. Inadequate water purification, poor pest control, and unclean storage were among these infractions, which promoted microbial degradation and ultimately exacerbated the original infection. Toxins may rise due to degradation (such as hydrolysis in humid storage), but production is the main problem because untested batches did not follow good manufacturing procedures (GMP).

As demonstrated by the purported sample switching by Haryana officials in the Gambia bribery case, supply networks increase risks as informal distributors avoid oversight. Pharmacologically, adulterants alter bioavailability; DEG's solubility boosts activity but results in distinct nephrotoxicity. Every year, 80% of Indian youngsters steal over-the-counter formulas, and the allure of syrup in homes with low literacy rates conceals risks. Export biases make matters worse because only foreign syrups will require further testing after 2022, endangering domestic markets. One of the best examples of global ripple effects is the Gambia case, where the WHO blacklisted fifteen Indian businesses [27,28].

Policy Deficiencies and Gaps: Where India Lags

CDSCO monitoring is required by India's Drugs and Cosmetics Act (1940, updated 2023), however enforcement is lacking. Corner-cutting is encouraged by the decriminalization of "not-of-standard-quality" offenses after the Gambia incident. Regulators are understaffed—one inspector for every 1,000 units—and inspections have lapsed for up to two years, as in Sresan pharmaceuticals. Domestically, there are no standard DEG-specific testing; QR traceability (2023 for 300 medicines) focuses on counterfeits rather than inferior excipients. State-specific FDAs differ: Inspectors were suspended in Tamil Nadu, but national coordination is lacking.

Over 1,000 “not-of-standard” samples are not prosecuted annually due to inadequacies in pharmacovigilance and export-domestic inequalities. WHO calls them "deep concerns," and risk-based audits are advised. Despite 2025 warnings against under-twos, pediatricians observe that there are no child-specific prohibitions, and pharmacologists lament the lack of excipient guidelines [29].

International harmonization of excipient-testing standards is desperately needed, as evidenced by the numerous global failures this study finds. While there are accepted analytical techniques for identifying DEG, their application varies by nation. Enforcing batch-wise testing of excipients, bolstering laboratory infrastructure, and enhancing digital traceability in pharmaceutical supply chains are crucial actions. By implementing more dependable recall protocols, frequent surprise inspections, and real-time monitoring, regulatory bodies must move from reactive to proactive oversight. Clinical awareness must also be increased. In clusters of children with acute renal damage, early diagnosis of DEG poisoning could greatly improve outcomes [30].

Recommendations and Future Prevention

Every year, CDSCO conducts risk-based audits that cover at least 20% of pediatric manufacturing facilities, particularly rural suppliers, using AI-enabled supply-chain tracking to identify early anomalies; Expanded traceability is supported by universal QR codes on all syrups and user-friendly apps for real-time verification; pediatric safety initiatives, like the IAP/IPA-led "Syrup-Safe" program, should educate parents about safer alternatives, like inhalers, and tighten restrictions on the sale of over-the-counter syrup to children under five. Two ways to tighten sanctions are to re-criminalize adulteration with 5–10 year prison sentences and to use WHO systems to internationally blacklist repeat offenders.

Harmonizing Indian rules with USFDA and EU quality standards and bolstering the WHO Member State Mechanism for coordinated investigations are two ways to improve international protections. Joint pharmacology-pediatrics training courses on adulterant identification and structured reporting via PvPI should be part of academic integration. Long-term policy modeling suggests that these multilayered reforms might reduce contamination-related events by up to 50% in five years. The need to extend the 2025 emergency restrictions throughout India in the near future is highlighted by physician alerts and urgent statewide recalls.

Enhancing production techniques is essential. Requiring batch testing for DEG

and EG in all excipients, along with digital supply-chain traceability and third-party audits, would significantly reduce contamination risks. Regulators ought to enforce post-marketing surveillance, conduct regular surprise inspections, and take an active role in global alert-sharing networks. To identify tainted items early, public health institutions must increase the capacity of toxicology labs and communicate promptly during recalls. When newborns experience unexplained acute renal injury, especially in clusters of identical instances, clinicians should be educated to recognize DEG poisoning [31,32].

Conclusion

DEG contamination of pediatric cough syrups presents a significant concern to public health even though it is completely avoidable. Over a 15-year span, this PRISMA-guided systematic analysis reveals recurring patterns of excipient adulteration, manufacturing carelessness, and insufficient regulatory enforcement. To stop more pediatric deaths, it is essential to strengthen excipient verification, enforce thorough batch-level testing, and guarantee integrated regulatory control. The safety of children, who suffer the most from these catastrophes, depends on a pharmaceutical system that prioritizes quality, accountability, and transparency. Thus, global reforms need to be put into effect immediately.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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