REVIEW ARTICLE

Cough syrup tragedies: Global incidents, causes, and regulatory lessons

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Abstract

Cough syrups are among the most widely used pediatric medications worldwide. However, recurring mass-poisoning events due to contamination with diethylene glycol or ethylene glycol have caused numerous child deaths over nearly a century. From the 1937 *Elixir Sulfanilamide* tragedy in the United States to the recent *Coldrif* incident in India (2025), these disasters highlight failures in manufacturing, excipient sourcing, and regulatory vigilance. This review summarizes the chemical and toxicological basis of glycol poisoning, presents a chronological analysis of major global incidents, and examines regulatory reforms enacted to prevent recurrence. It emphasizes the necessity of rigorous testing of raw materials and finished oral liquids, international harmonization of quality standards, and transparent pharmacovigilance to protect vulnerable populations.

Key words: Child deaths, cough syrup poisoning, diethylene glycol, ethylene glycol, pharmacovigilance, regulatory failure

INTRODUCTION

Cough and cold syrups are common over-the-counter and prescription formulations designed to relieve respiratory symptoms. Their popularity, especially among children, stems from ease of administration and palatable taste. Despite these benefits, the history of pharmaceutical toxicology has repeatedly shown that liquid dosage forms can become fatal when contaminated with industrial solvents or improperly manufactured excipients.[1,2]

Diethylene glycol (DEG) and ethylene glycol (EG), low-cost substitutes for pharmaceutical-grade glycerin or propylene glycol, have been implicated in multiple poisoning episodes across continents.[3] Pediatric patients are particularly vulnerable because of their low body weight, immature renal systems, and frequent use of syrups for self-limited illnesses.[4] The recurrence of such tragedies despite regulatory progress underscores persistent global disparities in drug quality assurance.[5]

HISTORICAL BACKGROUND OF COUGH SYRUP TOXICITY

The first major recorded disaster, the *Elixir Sulfanilamide* tragedy of 1937 in the United States, killed more than 100 people after DEG was used as a solvent for sulphanilamide.[6] At the time, manufacturers were not legally required to test for toxicity before marketing a formulation. Public outrage prompted enactment of the Federal Food, Drug, and Cosmetic Act of 1938, mandating pre-market safety evaluation by the U.S. Food and Drug Administration (FDA).[7]

This event became a cornerstone of modern pharmaceutical regulation, emphasizing that excipients are not inert and that manufacturing oversight must extend beyond the active ingredient. Unfortunately, subsequent decades revealed that similar mistakes continued to occur in different socioeconomic settings.[8]

CHEMICAL BASIS OF COUGH SYRUP TOXICITY

DEG and EG

DEG ($C_4H_{10}O_3$) and EG ($C_2H_6O_2$) are colorless, odorless, viscous liquids widely used as industrial antifreeze, solvents,

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and plasticizers.[9] They resemble glycerin in appearance and viscosity, making them potential adulterants when pharmaceutical-grade glycerin is costly or scarce.

Mechanism of Toxicity

After ingestion, EG and DEG are metabolized by alcohol dehydrogenase to toxic metabolites such as glycolic acid, oxalic acid, and diglycolic acid. These compounds induce metabolic acidosis, renal tubular necrosis, and multi-organ failure.[10] The estimated lethal dose of DEG in humans is about 1 mL/kg, though clinical outcomes depend on co-ingestants and treatment delays.[11]

Clinical and Diagnostic Features

Symptoms generally appear within 24–72 h: Vomiting, altered sensorium, abdominal pain, oliguria, and eventual acute kidney injury.[12] Laboratory findings include high-anion-gap metabolic acidosis, elevated creatinine, and oxalate crystalluria. Gas chromatography (GC) or high-performance liquid chromatography remain definitive diagnostic methods.[13]

GLOBAL COUGH SYRUP DISASTERS: A CHRONOLOGICAL REVIEW

The Elixir Sulfanilamide Incident (USA, 1937)

Mass poisoning in 1937 resulted when DEG was used to dissolve sulfanilamide to make a raspberry-flavored elixir. The manufacturer, S.E. Massengill Co., performed no toxicity testing. More than 100 deaths were documented across 15 states.[6,14] This case led directly to comprehensive U.S. legislation requiring safety testing before drug approval.

Haiti (1995–1996)

In Port-au-Prince, at least 86 children died after consuming paracetamol syrup prepared with DEG-contaminated glycerin imported from China.[15] The Centers for Disease Control and Prevention (CDC) confirmed DEG presence in both the syrup and the excipient stock. The tragedy exposed weaknesses in excipient supply-chain verification in low-resource settings.

Panama (2006)

Panama experienced a similar epidemic of renal failure after DEG-adulterated glycerin was used in cough and allergy syrups distributed through the public health system.[16] Investigations found that the contaminated glycerin had traversed multiple intermediaries between the Chinese manufacturer and the Panamanian authorities without testing certification. Over 100 deaths were reported. The case underscored the dangers of complex, opaque ingredient supply chains.[17]

Nigeria (2008–2009)

The Nigerian incident involved DEG contamination of acetaminophen syrups marketed for children.[18] More than 80 pediatric fatalities were attributed to acute renal failure. Nigeria's National Agency for Food and Drug Administration and Control responded by banning several local manufacturers and enforcing stricter testing of excipients.[19]

The Gambia (2022)

In 2022, 66 child deaths in The Gambia were linked to four imported cough and cold syrups found to contain DEG and EG.[20] The World Health Organization (WHO) issued a global medical product alert, emphasizing the risk of contaminated pediatric formulations exported from India.[21] The case attracted international attention to the regulatory oversight of small-scale Indian exporters supplying African markets.[22]

Uzbekistan (2022)

Later the same year, Uzbekistan reported at least 20 child deaths associated with Dok-1 Max syrup and related preparations manufactured in India.[23] Analytical testing again revealed DEG and EG contamination. The Uzbek Ministry of Health suspended distribution and initiated criminal proceedings against local representatives.[24] WHO and India's Central Drugs Standard Control Organization (CDSCO) began coordinated investigations.[25]

India (2025) — Coldrif Disaster

In 2025, the Coldrif cough syrup, produced by Sresan Pharmaceuticals Ltd. in Tamil Nadu, was linked to at least 24 child deaths in Madhya Pradesh.[26] Government laboratory analysis revealed DEG concentrations approaching 48.6 %, far exceeding the permissible 0.10% limit.[27] Inspections uncovered poor manufacturing practices: rusted equipment, absence of air-handling units, and lack of qualified personnel.[28] The manufacturer's license was revoked, and DEG testing of finished oral liquids was made mandatory nationwide.[29] This event marked India's most severe domestic pharmaceutical safety crisis in recent years.

EPIDEMIOLOGICAL AND CLINICAL FEATURES

Across all events, children under 10 years constituted the majority of victims.[30] The common clinical presentation included vomiting, lethargy, and progressing renal failure. Laboratory analyses consistently detected elevated creatinine

levels and metabolic acidosis. Mortality rates ranged from 40% to 90%, depending on early detection and availability of hemodialysis.[31]

Epidemiological investigation usually traced the source to contaminated glycerin or propylene glycol imported from unverified suppliers.[32] In developing nations, weak surveillance and fragmented drug-distribution systems delayed detection and recall.[33]

MANUFACTURING AND QUALITY-CONTROL FAILURES

Adulterated Excipients

The repeated substitution of industrial-grade glycerin for pharmaceutical-grade material lies at the core of most disasters.[34] Industrial glycerin may contain up to 30–50% DEG due to inadequate purification. In the absence of routine analytical verification, such material enters pharmaceutical production unnoticed.[35]

Testing Deficiencies

Although pharmacopoeias mandate identity and purity testing of excipients, compliance is inconsistent. Many small-scale manufacturers rely on supplier certificates of analysis without independent verification.[36] Furthermore, earlier regulations often required DEG testing only for raw glycerin, not for finished formulations.[37]

Documentation and Oversight Gaps

Inspections after the 2025 Coldrif incident revealed missing batch records, uncalibrated analytical instruments, and falsified test certificates.[38] Such findings illustrate systemic Good Manufacturing Practices (GMP) non-compliance, particularly in facilities supplying local markets.

Economic Drivers

Financial pressure to reduce production costs and supply-chain disruptions – such as those seen during pandemics – encourage use of cheaper, untested solvents.[39] Without rigorous supplier audits, DEG and EG can easily replace legitimate excipients.

REGULATORY AND PHARMACOPEIAL RESPONSES

United States and International Precedents

After 1937, the U.S. FDA gained authority to demand pre-market safety data, factory inspections, and labeling oversight.[7] These powers drastically reduced the incidence of such poisonings in the United States. Other nations gradually adopted similar frameworks.

WHO

Following the Gambian and Uzbek incidents, the WHO issued Medical Product Alerts in 2022 and 2023, warning all national regulatory authorities to test syrups for DEG/EG.[21] WHO's global alert system now lists DEG testing as a core requirement for oral liquid safety surveillance.[40]

India — CDSCO and Indian Pharmacopoeia Commission

After multiple international episodes, the CDSCO in 2023 mandated DEG/EG testing for both raw materials and finished oral liquid formulations.[29] The Indian Pharmacopoeia 2022 was amended through Addendum 09 (2024) to specify an upper limit of 0.10% for DEG and EG, verified by GC.[41]

Post-2025, CDSCO ordered nationwide inspections of all manufacturers of pediatric syrups, cancellation of licenses for non-compliance, and enhanced testing at state drug control laboratories.[42]

Regional and Global Harmonization

The Pan American Health Organization and the European Medicines Agency have similarly emphasized excipient traceability and supplier qualification.[43] The International Pharmaceutical Excipients Council (IPEC) guidelines now include specific supplier-audit templates for glycerin and propylene glycol.[44]

ANALYTICAL DETECTION AND QUALITY CONTROL STRATEGIES

Routine Testing Requirements

The reliable detection of DEG and EG contamination depends on the use of specific chromatographic techniques. GC and GC–mass spectrometry remain the gold standards for excipient and product analysis.[45] The United States Pharmacopeia and Indian Pharmacopoeia prescribe GC methods with flame ionization detection for quantifying glycol contaminants in glycerin and propylene glycol.[46]

Field and Rapid Screening Tools

Developing countries often lack sophisticated analytical infrastructure. Therefore, the WHO has promoted low-cost colorimetric methods using sodium periodate oxidation or potassium permanganate screening as preliminary tools

before GC confirmation.[47] Although less precise, these field assays provide early warnings for contaminated batches, allowing regulators to act swiftly.

Supplier Verification and Audit Trails

Ensuring the quality of excipients demands transparent supply-chain traceability. Each batch of glycerin or propylene glycol must include a verifiable certificate of analysis, supplier audit reports, and documented testing at the manufacturer's site.[48] The International Council for Harmonization (ICH) and IPEC-PQG GMP Guide for Excipients recommend full documentation of production sites, purification methods, and lot traceability.[49]

Analytical Method Validation

Validated analytical procedures ensure the reliability of detection. Parameters such as specificity, linearity, accuracy, precision, and detection limit must comply with ICH Q2 (R1) guidelines.[50] This validation helps prevent false negatives that could allow contaminated material to reach consumers.

PUBLIC HEALTH IMPLICATIONS

Mortality and Morbidity Burden

Cough syrup poisoning disproportionately affects children, with mortality often exceeding 70% when treatment is delayed.[30,51] The impact extends beyond individual deaths to include widespread loss of public trust in healthcare systems and local pharmaceutical industries.[52] Survivors may experience chronic renal insufficiency or neurological deficits, necessitating long-term medical care.[53]

Socioeconomic Consequences

Each outbreak incurs massive economic and social costs. For instance, the 2022 Gambian crisis led to the suspension of multiple Indian export licenses, resulting in losses exceeding USD 10 million and diplomatic tension between nations.[22,54] Domestic production shutdowns, product recalls, and compensations further strain the economies of affected regions.[55]

Psychological and Community Trauma

Parents of victims often endure long-term psychological trauma, compounded by mistrust of medications and healthcare workers.[56] Public fear may also drive irrational avoidance of legitimate medicines, exacerbating untreated illnesses.[57]

TREATMENT AND CLINICAL MANAGEMENT

Early Diagnosis

Prompt recognition of DEG or EG poisoning is vital. Clinicians should suspect glycol toxicity when children with recent syrup ingestion present with vomiting, altered mental status, and unexplained renal failure.[58] Laboratory confirmation with serum osmolality and anion-gap analysis provides initial diagnostic clues.[59]

Therapeutic Interventions

The primary antidotes – fomepizole and ethanol – inhibit alcohol dehydrogenase, preventing the formation of toxic metabolites.[60] Intravenous bicarbonate corrects metabolic acidosis, while hemodialysis removes both parent compounds and metabolites.[61] Supportive management includes maintaining fluid balance and monitoring renal function.

Limitations in Resource-Limited Settings

Unfortunately, most incidents occur in low-resource countries lacking fomepizole availability or dialysis capacity.[62] Delayed hospital presentation further limits survival chances. Strengthening emergency preparedness and training health personnel in early identification remains essential.[63]

LESSONS LEARNED FROM GLOBAL INCIDENTS

Common Patterns

An analysis of global data reveals several repeating themes: Use of unverified industrial-grade excipients, Absence of routine DEG testing for either raw materials or finished products, Weak enforcement of GMP, and Delayed response to initial poisoning reports due to poor pharmacovigilance.[64]

Strengthening Regulatory Oversight

Regulatory bodies must shift from reactive to preventive frameworks. Mandatory lot-wise excipient testing, periodic manufacturer audits, and a centralized excipient registration system can reduce risks.[65]

In India, CDSCO's 2025 policy mandating DEG testing for all cough syrups marked significant progress. Similar models could be adapted globally under WHO coordination.[29,66]

Enhancing Pharmacovigilance

Post-marketing surveillance needs expansion beyond adverse drug reaction reporting. Integration of toxicovigilance networks, linking hospitals and public laboratories, can expedite the detection of contamination-related clusters.[67]

Education and Ethical Responsibility

Manufacturers, pharmacists, and healthcare professionals share a moral responsibility to ensure medicine safety. Incorporating pharmaceutical ethics and quality assurance modules into pharmacy curricula helps reinforce this culture.[68]

Public awareness campaigns about the dangers of counterfeit or unregulated syrups can further prevent tragedies.[69]

FUTURE DIRECTIONS AND PREVENTIVE STRATEGIES

Digital Traceability Systems

Emerging technologies such as blockchain can offer immutable supply-chain records for excipients, reducing adulteration risk.[70] Digital batch tracking allows real-time verification of raw material origins.

Global Harmonization of Standards

To avoid discrepancies, national pharmacopoeias should adopt unified DEG testing thresholds and validated methods under WHO guidance.[71] The creation of an International DEG Monitoring Consortium has been proposed to consolidate analytical data worldwide.[72]

Public–Private Partnerships

Collaborative networks between governments, academia, and pharmaceutical industries can finance analytical infrastructure, training, and emergency response mechanisms.[73] Incentivizing local production of pharmaceutical-grade excipients could also reduce dependence on uncertain imports.[74]

Ethical Supply Chain Certification

A global certification framework for "Safe Excipient Suppliers," similar to ISO accreditation, could enhance accountability. Independent audits and online publication of supplier compliance data would promote transparency.[75]

CONCLUSION

Cough syrup disasters are among the most preventable tragedies in pharmaceutical history. Despite regulatory advancements since 1937, repeated incidents in developing nations reveal persistent vulnerabilities in quality assurance and global supply chains. The lessons are unequivocal: Safety testing must extend to every component of a drug formulation, including excipients; regulatory vigilance must be continuous, not episodic; and ethical responsibility must underpin every stage of pharmaceutical manufacturing.

The 2025 Coldrif disaster serves as a stark reminder that low-cost shortcuts in excipient sourcing can exact an unbearable human price. Only through unified international action – anchored in science, transparency, and accountability – can future generations be protected from such preventable loss.

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