SAFE PEDIATRIC MEDICATION PRACTICES

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AGENDA

- INTRODUCTION
- MEDICATION ERRORS IN CHILDREN
- POLYPHARMACY AND DRUG INTERACTION
- PEDIATRIC MEDICATION SAFETY
- MEDICATION RECONCILIATION
- FUTURE STRATEGIES

AGE CLASSIFICATION OF PEDIATRIC PATIENTS

- Heterogeneous group
- Adjusted age
- Immature renal and hepatic clearance
- Immature CNS
- Unique neonatal disease states
- Small total blood volume

- High body surface-area-to weight ratio
- Immature blood brain barrier
- Less predicable oral absorption
- Immature hepatic and renal clearance

- CNS maturation
- Immune system development
- Total body growth
- Renal clearance

- Psychomotor development
- Physical growth
- Onset of puberty
- Neurocognitive development

- Sexual maturation
- Hormonal changes
- Height
- Neurocognitive development

Preterm newborn infants	Term Newborn (0-27 days)	Infants & Toddlers (28 days to 23 months)	Children (2 to 11 years)	Adolescents (12 to 16-18 years)

E11 Clinical Investigation of Medicinal Products in the Pediatric Population. FDA Dec 2000

A SHOCKING INCIDENT

- A 5-year-old child with epilepsy was prescribed Tablet **CLOBAZAM (an antiepileptic)**. At the pharmacy, the drug was confused with tablet **CLOZAPINE (an antipsychotic)** due to similar packaging and name.
- After a few doses, the child developed excessive sedation, drooling, and tachycardia.

Where was the problem?

Why it happened?

How can we prevent it?

This was look alike sound alike drug error.(LASA)

ANOTHER SHOCKING SCENARIO

- A 6-month-old infant admitted for pneumonia was prescribed **IV gentamicin 4 mg/kg once daily**. The correct dose was **20 mg (in 2 mL solution)**. A nurse miscalculated and administered the **undiluted stock (40 mg/mL)** instead of diluting it. This resulted in the infant receiving **ten times the intended concentration**. Shortly after infusion, the baby developed apnea, bradycardia, and required resuscitation.

Why the problem happened?

How can it be prevented?

WHAT IS A MEDICATION ERROR ?

Any **PREVENTABLE** event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

ISMP 2001

Advancing the responsible use of medicines

Applying levers for change

OCTOBER 2012

IMS INSTITUTE FOR HEALTHCARE INFORMATICS

4. RIGHT MEDICINE TO THE RIGHT PATIENT: PREVENT MEDICATION ERRORS

Medication errors contribute 9% of the world's total avoidable cost due to suboptimal medicine use.

A total of 0.7% of global total health expenditure (THE), or 42Bn USD worldwide, can be avoided if medication errors are prevented.

Global Calculations which include 186 countries:

IMS MIDAS, 2009 and 2011; World Bank 2009; WHO 2009; USD in 2011

MEDICATION ERRORS : INDIAN EXPERIENCE

M Parihar, G PR Passi. Medical Errors in pediatric practice. Ind Pediatrics 45 2008; 586-89.

- Prospective study in a Teaching Hospital at Indore, MP - 1286 children in PICU
- Out of the total 457 errors identified, medication errors 313 (68.5%)
- Majority were dosing errors (45.5%)
- Morbidity was nil in 375 (82%), mild in 49 (10.7%), moderate in 22 (4.8%) and severe in 11 (2.4%) errors.

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Original Research Article

Medication errors reported in a tertiary care private hospital in Eastern India: a three years experience

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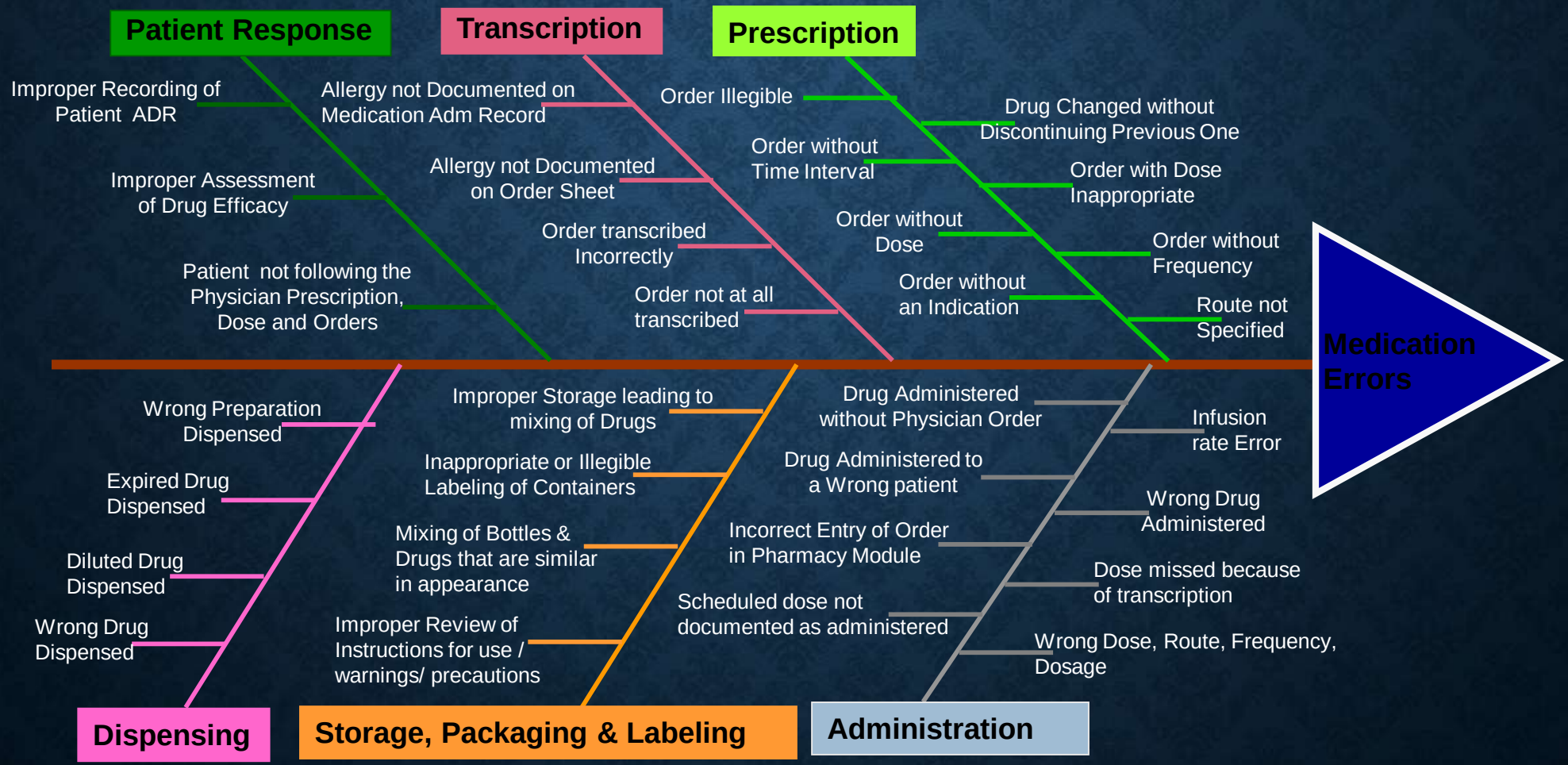
WHO's Global Patient Safety Challenges

First Challenge -2005
Clean care is safer care

Second Challenge -2007
Safe Surgery Save Lives

Third Challenge -2017
Medication without Harm
Currently ongoing

ROOT CAUSE ANALYSIS OF MEDICATION ERROR



Note: Errors are more frequent during “Prescription” and “Administration” stage

A SHOCKING INCIDENT

- A 5-year-old child with epilepsy was prescribed Tablet **CLOBAZAM (an antiepileptic)**. At the pharmacy, the drug was confused with tablet **CLOZAPINE (an antipsychotic)** due to similar packaging and name.
- After a few doses, the child developed excessive sedation, drooling, and tachycardia.

Where was the problem?

Why it happened?

How can we prevent it?

This was look alike sound alike drug error.(LASA)

Corrective Measures :

- The error was identified when parents brought the medicine strip back.
- Clozapine was discontinued immediately.
- Supportive care (oxygen, IV fluids, monitoring vitals) was given.
- No long-term complications occurred.

Preventive Measures :

- Implementation of **Tall Man lettering** in labels (e.g., cloBAZam vs. cloZAPine).
- Pharmacist double-check of prescriptions, especially for pediatric patients.
- Education of parents to **verify drug name and strength** at the pharmacy.
- Encourage reporting of LASA errors to pharmacovigilance centers for system-level change.
- Clearly writing the drug name in capital letters to prevent confusion.

ANOTHER SHOCKING SCENARIO

- A 6-month-old infant admitted for pneumonia was prescribed **IV gentamicin 4 mg/kg once daily**. The correct dose was **20 mg (in 2 mL solution)**. A nurse miscalculated and administered the **undiluted stock (40 mg/mL)** instead of diluting it. This resulted in the infant receiving **ten times the intended concentration**. Shortly after infusion, the baby developed apnea, bradycardia, and required resuscitation.

Why the problem happened?

How can it be prevented?

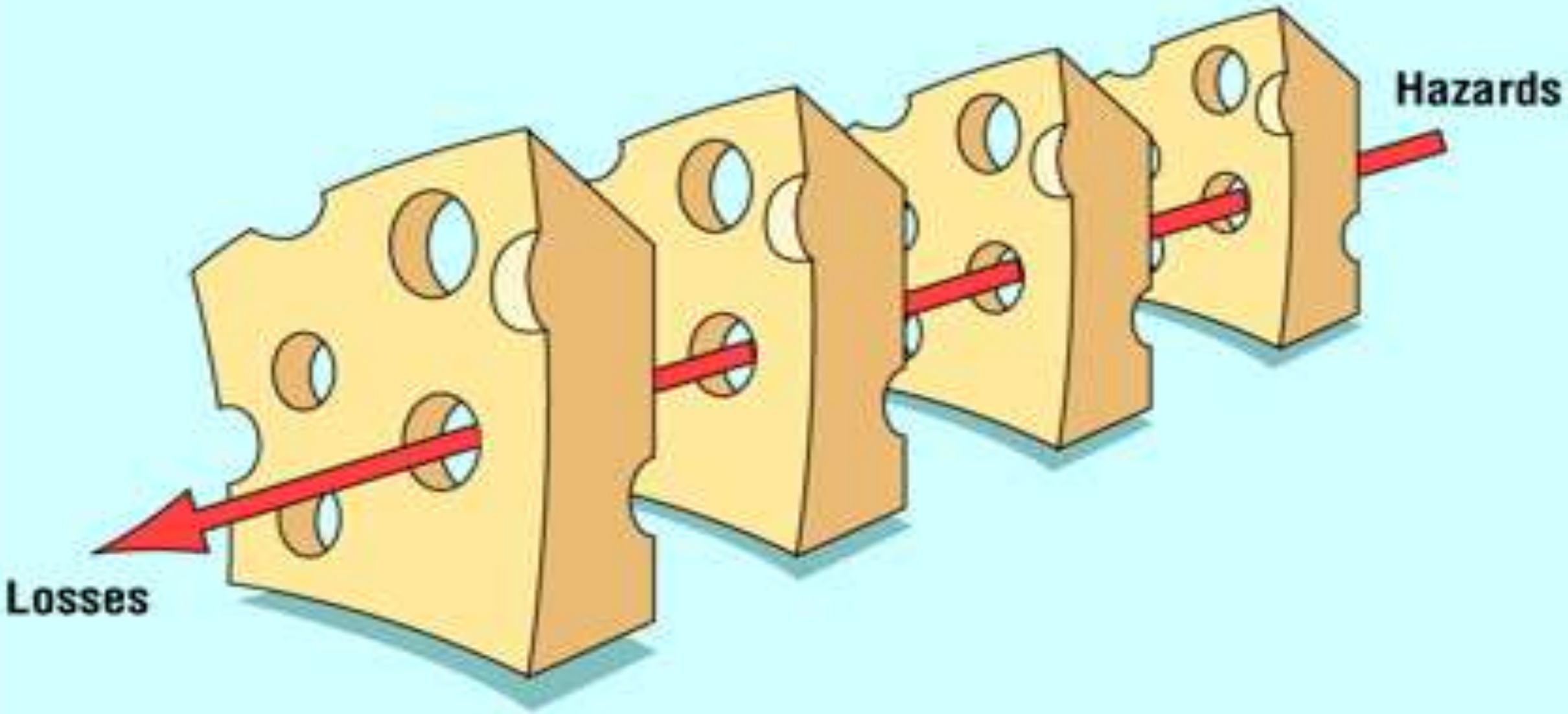
Corrective Measures:

- Immediate cessation of the infusion.
- The infant was shifted to NICU and given **respiratory support** (bag and mask ventilation, then oxygen therapy).
- Serum gentamicin levels and renal function were monitored.
- Subsequent doses were withheld, and alternative antibiotics were used.

Preventive Measures:

- **Standard dilution charts** for pediatric IV drugs displayed in wards.
- Use of **prefilled, ready-to-use syringes** in pediatric setups to minimize calculation errors.
- Double-checking of pediatric IV drug preparation by **two nurses/pharmacists** before administration.
- Continuous training on **high-alert drugs** like aminoglycosides, insulin, heparin in pediatric units.

Medication Errors signify faulty systems and not faulty professionals



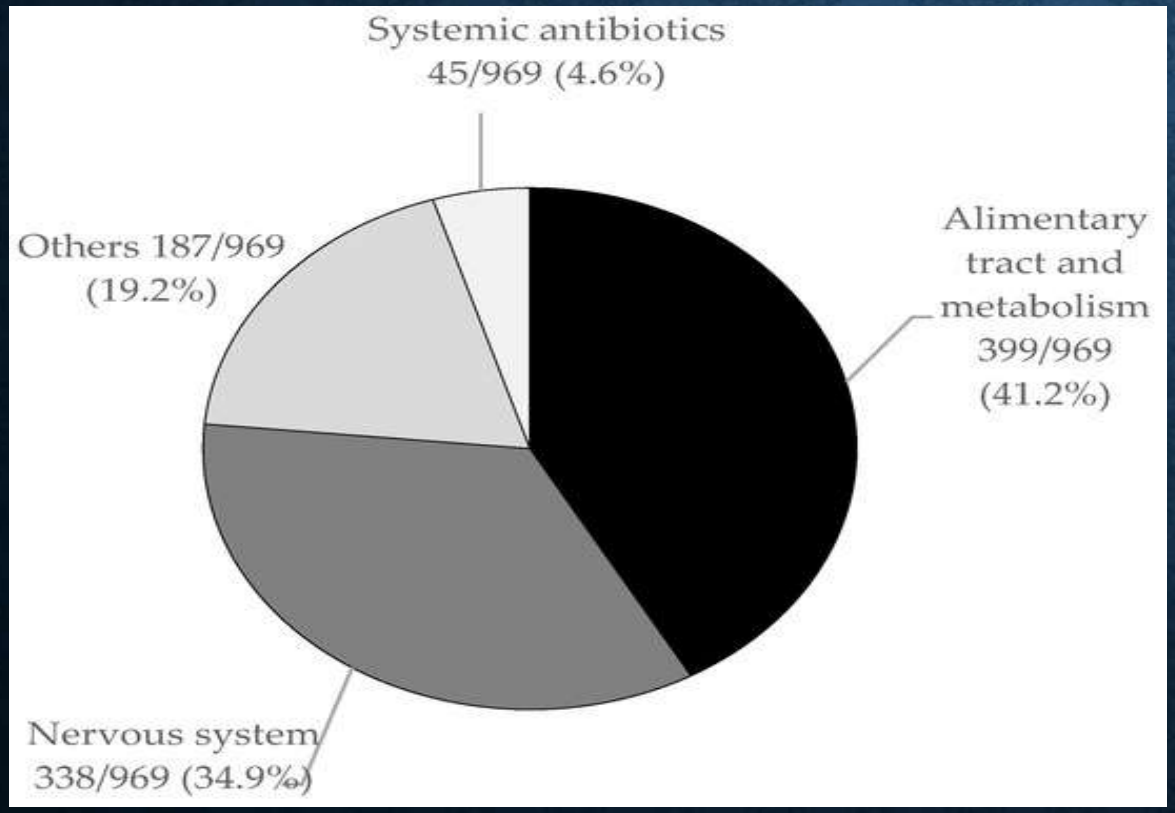
Swiss Cheese Model of Risk analysis & management

MEDICATION ERRORS IN CHILDREN

- Dosing errors (mg vs. mL confusion), off-label use without clear evidence, and incorrect routes of administration are prevalent everywhere.
- It has been estimated that in some countries 6 medication errors approximately 6-7% of hospital admissions appear to be medication related, with over two-thirds of these considered avoidable and thus, potentially due to errors.

POLYPHARMACY AND DRUG INTERATIONS

- Increasing use of medications, especially in adolescents with chronic diseases or mental health issues, raises the risk of adverse drug interactions.



Zanin, A., Baratiri, F., Roverato, B., Mengato, D., Pivato, L., Avagnina, I., Maghini, I., Divisic, A., Rusalen, F., Agosto, C., Venturini, F., & Benini, F. (2024). Polypharmacy in Children with Medical Complexity: A Cross-Sectional Study in a Pediatric Palliative Care Center. *Children*, *11*(7), 821. https://doi.org/10.3390/children11070821

ADVERSE DRUG REACTION

- Adverse drug reactions (ADRs) are defined by the World Health Organization (WHO) as “a response to a drug which is noxious, and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function

KNOWN RISK FACTORS FOR ADRS IN CHILDREN

- Polypharmacy
- Previous adverse reaction to another drug
- Female sex
- Impaired liver or renal function
- Off-label and unlicensed drug use
- Genetic polymorphisms

MINIMIZING PEDIATRIC MEDICATION ERRORS

- Weight-Based Dosing: Essential in pediatrics to avoid over- or under-dosing. Use of standardized dosing charts or software for calculations.
- Electronic Prescribing and Double Checks: Incorporation of computerized provider order entry (CPOE) systems and pharmacist-led verification, particularly for high-alert medications.
- Medication Reconciliation: During transitions in care (e.g., hospital admission or discharge), verifying current medications helps prevent omissions or duplications.
- Caregiver and Patient Education: Emphasis on clear instructions, pictorial aids, and teach-back methods to enhance comprehension.

ONE SIZE DOES NOT FIT ALL

- **Formulation & Taste Adaptation**: Young children often refuse pills and dislike adult flavors.

- Pediatric-friendly forms—liquid suspensions, chewables, dissolvable tablets, capsules, and flavoring packs—improve acceptability and ensure correct dosing.

- **Dose Precision & Pharmacokinetics**: Children's bodies metabolize drugs differently. Accurate weight-based dosing and standardized devices (e.g., oral syringes) are essential. Vigilant monitoring avoids under- or overdosing, since toxicity thresholds are closer at younger ages.

MEDICATION QUALITY AFFECTS SAFETY

F.No.28025/52/2025-SAS.II/EMR
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Nirman Bhawan, New Delhi-110011

Dated: 3rd October, 2025

To,
The Director Health Services,
All States/Union Territories.

Sub: **Advisory on Rational Use of Cough Syrups in Paediatric Population - reg.**

Sir/Madam,

In our continuous efforts to ensure rational drug use and patient safety in paediatric care, this advisory reiterates the judicious prescribing and dispensing of cough syrups for children. Most acute cough illnesses in children are self-limiting and often resolve without pharmacological intervention.

2. Cough and cold medications should not be prescribed or dispensed to children under 2 years. These are generally not recommended for ages below 5 years and above that, any use should follow careful clinical evaluation with close supervision and strict adherence to appropriate dosing, the shortest effective duration and avoiding multiple drugs combinations. Further, the public may also be sensitized regarding adherence to prescription by the Doctors.

3. Non-pharmacological measures, including adequate hydration, rest, supportive measures should be the first-line approach.

4. All healthcare facilities and clinical establishments must ensure procurement and dispensing of products manufactured under Good Manufacturing Practices and formulated with pharmaceutical-grade excipients. Sensitization of prescribers and dispensers across public and private sectors is essential to uphold these standards of care.

5. It is requested that the all State/UT Health Departments, District Health Authorities, and all Clinical Establishments/healthcare facilities under your jurisdiction should implement and disseminate this advisory across government dispensaries, PHCs, CHCs, district hospitals, and medical institutions.

Yours faithfully,

(Dr. Sunita Sharma)
DGHS

Copy to:
1. Drug Controller General of India, CDSCO
2. All State Drug Controllers
3. PSO to Secretary (Health & Family Welfare), MoHFW, Nirman Bhawan, New Delhi.
4. AS & MD, MoHFW, Nirman Bhawan, New Delhi.
5. All Institution Heads of Central Government Hospitals
6. Directors of all AIIMS
7. Directors of PGI Chandigarh, JIPMER Puducherry.
8. All Regional Directors, RoHFW.

GOVERNMENT OF MAHARASHTRA
FOOD AND DRUGS ADMINISTRATION

Press Note

Public Alert – Stop Use Notice

Stop Use Notice Regarding Coldrif Syrup (Batch No. SR-13) Due to Toxic Adulteration

Date: 05-10-2025

The Food and Drugs Administration, Maharashtra, has been alerted to reports of the tragic deaths of children in Madhya Pradesh and Rajasthan, **Coldrif Syrup (Phenylephrine Hydrochloride, Chlorpheniramine Maleate Syrup),** Batch No. SR-13, Mfg. Dt. May-2025, Exp. Dt. April-2027, manufactured by **Sresan Pharma, Sunguvarchathiram, Kancheepuram District, Tamil Nadu,** which has been allegedly adulterated with **Diethylene Glycol (DEG),** a toxic substance.

In view of this, all the licensee and public hereby instructed to **immediately stop sale/distribution/use of Coldrif Syrup, Batch No. SR-13,** if anybody is in possession, and report it to the local Drugs Control Authorities without delay.

The public may also report possession of the said drug directly to the Food and Drugs Administration, Maharashtra, through the toll-free number 1800222365 or by email to jchq.fda-mah@nic.in or ph- 9892832289

FDA Maharashtra officials are coordinating with the DCA authorities of Tamil Nadu, where the manufacturer **Sresan Pharma** is located, to track the distribution of the said product batch to Maharashtra. All Drugs Inspectors and Assistant Commissioners have been instructed to immediately alert retailers, wholesalers, and hospitals to freeze any stocks of the said product batch if available in the market.

The Food and Drugs Administration, Maharashtra is taking necessary measures in this regard. The public is urged to exercise caution to prevent any further risk to the life

Date: 05-10-2025

D. R. Gahane
Drug Contoller,
FDA Maharashtra

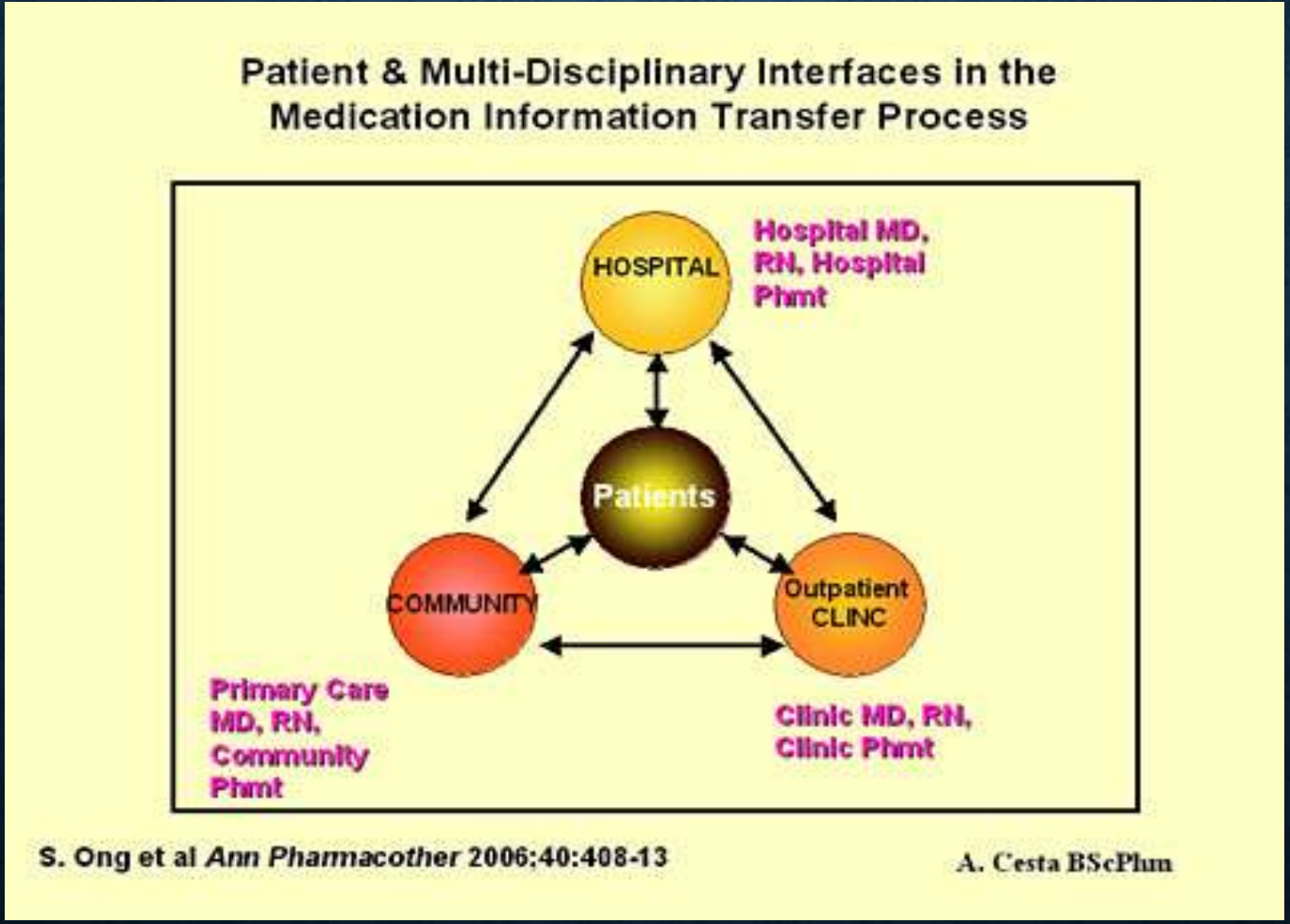
One size does not fit all

- **Recognizing Drug–Nutrition Interactions**: Some medications impair nutrient absorption (e.g., antiepileptics reduce vitamin D/calcium absorption). Proactive dietary planning or supplementation should accompany long-term prescriptions.

- **Child-Resistant Packaging & Safety**: Secure, child-resistant packaging is vital to mitigate risk of accidental ingestion, a leading cause of pediatric poisoning.

Taddio A, Appleton M, Bortolussi R, Chambers C, Dubey V, Halperin S, Hanrahan A, Ipp M, Lockett D, MacDonald N, Midmer D, Mousmanis P, Palda V, Pielak K, Riddell RP, Rieder M, Scott J, Shah V. Reducing the pain of childhood vaccination: an evidence-based clinical practice guideline. CMAJ. 2010 Dec 14;182(18):E843-55. doi: 10.1503/cmaj.101720. Epub 2010 Nov 22. PMID: 21098062; PMCID: PMC3001531.

MEDICATION RECONCILIATION IMPLEMENTATION



PEDIATRIC IMMUNIZATION SAFETY ISSUES

- Adverse Events Following Immunization (AEFIs): Ranging from minor (fever, soreness) to rare serious events (anaphylaxis). May undermine vaccine confidence despite a favorable risk-benefit profile.
- Cold Chain Failures: Compromised potency due to poor storage and transportation conditions.

PEDIATRIC IMMUNIZATION SAFETY ISSUES

- Vaccine Hesitancy: Driven by misinformation, cultural beliefs, and mistrust in healthcare systems.
- Missed Opportunities: Unvaccinated or partially vaccinated children due to systemic or logistical barriers.

STRATEGIES TO MINIMIZE IMMUNIZATION ISSUES

- Safe Administration Practices: Proper training of vaccinators. Use of auto-disable syringes and adherence to aseptic technique.
- Monitoring and Management of AEFIs: Active surveillance systems, immediate response protocols, and counseling for parents.
- Strengthening Cold Chain Management: Use of solar refrigerators, real-time temperature monitoring, and periodic audits and equipment maintenance.
- Community Engagement and Education: Transparent communication on vaccine benefits and safety. Collaboration with local leaders, schools, and influencers to build trust.

SUCCESS STORIES FROM INDIA

Integrated Child Development Services (ICDS)

- **Nutrition & Immunization Integration**
- Since its launch in **1975**, ICDS has delivered supplementary nutrition, preschool education, health check-ups, referral services, and **immunization** via Anganwadi centers for children under 6 and mothers.
- Early evaluations (1976–1980) found that integrating services greatly improved uptake: communities receiving combined nutrition, health, and immunization showed significantly better outcomes than those with separate service delivery.
- A 1988 study across ICDS and non-ICDS areas reported immunization coverage in ICDS regions at ~63–65% for BCG, DPT, and polio—compared with only ~22–28% in control areas

Tandon BN. A coordinated approach to children's health in India. Lancet. 1981 Mar 21;1(8221):650-3. PMID: 6110873.

SUMMARY

- Errors in prescribing, dosing, or administration are a leading cause of preventable harm in pediatric populations.
- Medication errors in Pediatric population signify faulty systems and not faulty professionals
- ADRs are common in children and polypharmacy, female gender and off-label dosing
- Electronic prescribing systems, double-check protocols, medication reconciliation, and caregiver education significantly reduce these risks.
- Risk minimization in pediatric medication and immunization is crucial to achieving optimal health outcomes.
- This involves not just medical protocols but also education, technology, policy, and community participation.

To conclude…

We must always remember that **“there are no biologically safe drugs**; there are only **safe physicians, nurses and pharmacists”.**

THANK YOU

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