



Canadian Medication Incident Reporting and Prevention System

Working Together to Prevent Harmful Medication Incidents

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On Behalf of the CMIRPS Coordinating Group

Canada's Virtual Forum Nov 2 2011



Tragic Medication Errors Result in Accidental Abortions and Premature Birth

By Avni Patel - August



Globe and Mail – June 12, 2002

Wrong injection causes death

Litany of errors

Incidents involving potassium chloride in Canada:

- 1 Potassium chloride (KCl) was administered via direct IV when the intended action was to flush an intravenous line with diluted sodium chloride. **Result: Patient died.**
- 2 KCl concentrate was used to reconstitute a drug for parenteral administration when the intended diluent was sterile water. **Result: Error was noted before administration.**
- 3 KCl concentrate was administered as a bolus injection – an injection given in high quantity, all at once – by a healthcare professional who was unaware that KCl concentrate cannot be given as a bolus but must be diluted in a minibag and given as an infusion. **Result: Patient died.**

- 4 A one-litre IV solution was prepared with potassium chloride and although it was administered at a very low rate, the incident was felt to be a near miss because of the potential for accidental overdose. **Result: Error was noted during administration.**
- 5 IV solutions containing KCl were administered as a fluid replacement in a patient requiring several litres of fluid in a short time frame. **Result: Hyperkalemia, patient died.**
- 6 Frances Marie Tanner, 84, received an intravenous injection of potassium chloride at the Peterborough Regional Health Centre on Jan. 21, 2002. **Result: Patient died.**

SOURCE: INSTITUTE FOR SAFE MEDICATION PRACTICES REPORT, MAY 2002. IMAGE: PHOTOGRAPHIC

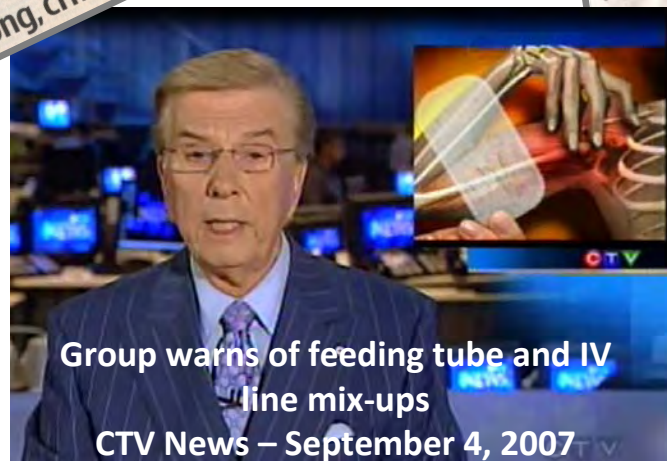
were accidentally given potassium chloride, three died and two were considered "near misses."

More cases could exist, said the institute's president, physician David U. While many hospitals have removed potassium chloride from nursing stations, he said, some doctors still demand to have it on hand, particularly in intensive-care units. And the drug manufacturers have a financial interest in maintaining their products' uniform packaging.

"The companies have just one assembly line, so they all look the same," he said. "It's an accident waiting to happen."

Researchers have suggested that perhaps 5,000 to 10,000 Canadians die because of medical error in hospitals every year.

The estimate is extrapolated from just one American study, however. A Canadian study was launched last month.



CMIRPS 
Canadian Medication Incident
Reporting and Prevention System

SCDPIM
Système canadien de déclaration et de
prévention des incidents médicamenteux

Objectives

- Introduce the Canadian Medication Incident Reporting and Prevention System (CMIRPS)
- Illustrate how the CMIRPS partners work together to enhance the safety of Canada's medication use system
- Discuss the importance of sharing information for the prevention of harmful medication incidents in Canada

CMIRPS Collaborating Organizations

- Health Canada
- Canadian Institute for Health Information (CIHI)
- Institute for Safe Medication Practices Canada (ISMP Canada)
- Canadian Patient Safety Institute (CPSI)

www.cmirps-scdpim.ca

Canadian Medication Incident
Reporting and Prevention System

Roles of the CMIRPS Collaborating
Organizations

What is CMIRPS and How Does it
work?

Benefits of CMIRPS

The Canadian Medication Incident Reporting and Prevention System

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

- Roles of the CMIRPS Collaborating Organizations
- What is CMIRPS and How Does it Work?
- Benefits of CMIRPS



CMIRPS

Canadian Medication Incident
Reporting and Prevention System



SCDPIM

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This presentation will use
fictional drug names and a fictional
scenario to illustrate how CMIRPS
works. Any resemblance to real
drugs or persons is purely
coincidental





Soltefam

- Anxiolytic
- Used for agitation in elderly

Faltasan

- For ADHD
- Contraindicated in hypertension, CAD
- New indication-smoking cessation



CMIRPS



Canadian Medication Incident
Reporting and Prevention System

SCDPIM

Système canadien de déclaration et de
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Types of Incident Reports



CMIRPS



Canadian Medication Incident
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Hazardous Situation Report

- Health professionals or consumers recognize potential for mix-ups with sound-alike names
- Also known as “Reportable Circumstance” in NSIR



Near Miss Incident Report

- Order for Faltasan is interpreted as Soltefam but error identified before medication is dispensed or administered



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No-harm incident Report

- Faltasan dispensed for Soltefam in community pharmacy; error identified by consumer after only one dose taken



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Harmful incident Report

- An elderly man is admitted to hospital. A family member states that the patient is taking Soltefam, but the admitting physician mistakenly interprets this as Faltasan. The patient receives Faltasan for three days and suffers a stroke.



CMIRPS Reporting Tools

- Canadian Institute for Health Information
 - National System for Incident Reporting (NSIR)
- ISMP Canada
 - Individual Practitioner Reporting system (IPR)
 - SafeMedicationUse.ca

Key Features of NSIR

- Web-based application for healthcare organizations
- Facilities can access own data and de-identified data from other facilities
- Integrated Tools
- Complements risk management systems



Messages

Submit

Find

Analyze

Profile

Administer

Help

Logout

Enter New Incident

Source

Impact

Discovery

Patient

Details

Drug

Investigation

* Source HCF

Select one...



HCF Case Record Number



Next

CMIRPS

Canadian Medication Incident Reporting and Prevention System (CMIRPS) Program

REPORT
a Medication Incident 

Practitioners:
Healthcare Professional - (e.g., nurse,
pharmacist, physician)



ISMP Canada:
Institute for Safe Medication Practices
Canada

SafeMedicationUse.ca

General Public:
Preventing harm from medication incidents is a
responsibility of health professionals. **Consumers**
like you can also play a vital role.

 **SHARE**   

ISMP Canada Activities for the CMIRPS:

- Reporting Systems for Medication Incidents
- A consumer medication safety reporting and learning program: SafeMedicationUse.ca
- Safety bulletins and alerts by ISMP Canada about medication incidents and prevention strategies
- Medication Safety Self-Assessment programs
- Root Cause Analysis workshops and frameworks
- Failure Mode and Effects Analysis workshops and

[CMIRPS Web site](#)

[Purpose of the CMIRPS](#)

[2010 Evaluation of ISMP Canada Activities](#)

[Bulletins](#)

[PDF Downloads](#)

ISMP Canada

- Individual Practitioner Reporting
 - collects reports directly from practitioners in settings where NSIR is not available
 - On-line or telephone
- SafeMedicationUse.ca
 - Consumer-friendly reporting mechanism
 - On-line or telephone



Preventing harm from medication incidents is a responsibility of health professionals. **Consumers like you** can also play a vital role.

Reporting Medication Incidents
benefits all Canadians.



REPORT NOW

- [About SafeMedicationUse.ca](#)
- [About Medication Incidents](#)
- [Why Report?](#)
- [Resolving Concerns About the Safety of Your Care](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [Your privacy](#)

Tell Us How We're Doing:

TAKE THE SURVEY



Latest News and Resources

- [Similar Patient Names Leads to Pregnant Woman Getting Wrong Prescription](#)
- [Safe Practices for Medication Use \(Take Charge of Your Medicines!\)](#)
- ["Take as Directed: Your Prescription for Safe Health Care in Canada" is now available in Canadian bookstores!](#)
"The authors provide helpful information that can guide Canadians on how to manage their health care, including safe medication use" says Sylvia Hyland, Vice President and Chief Operating Officer of ISMP Canada.
- Health Canada is reminding Canadians about using acetaminophen safely.
 - Read [Health Canada's Information Update on Acetaminophen](#)
 - Read the SafeMedicationUse article "[Spotlight on Acetaminophen](#)"
- [Angeliq Drug Samples Mistakenly Provided as Birth Control - Newsletter - PDF](#)
- [Working with Consumers and Patients to Prevent Medication Incidents: Early Learning from ISMP Canada's Consumer Reporting and Learning Program, \[www.SafeMedicationUse.ca\]\(#\) - Webinar - February 23, 2011](#)
- [Epinephrine Auto-Injectors - Know How to Use EpiPen and Twinject Properly - Newsletter - PDF](#)
- [Consumer Identifies Warfarin Error as the Cause of Unexpected Test Results -](#)

Privacy and Confidentiality

- Appropriate Measures for Protection of:
 - Privacy
 - Data security
- Data Sharing Agreements allow sharing of information

Analysis

- The purpose of analysis is to identify hazards, issues, contributing factors and underlying causes of medication incidents.
- Priority for analysis is given to reports where the incident led to or could potentially lead to serious outcomes.
- The analysis of individual reports is done by ISMP Canada and Health Canada.

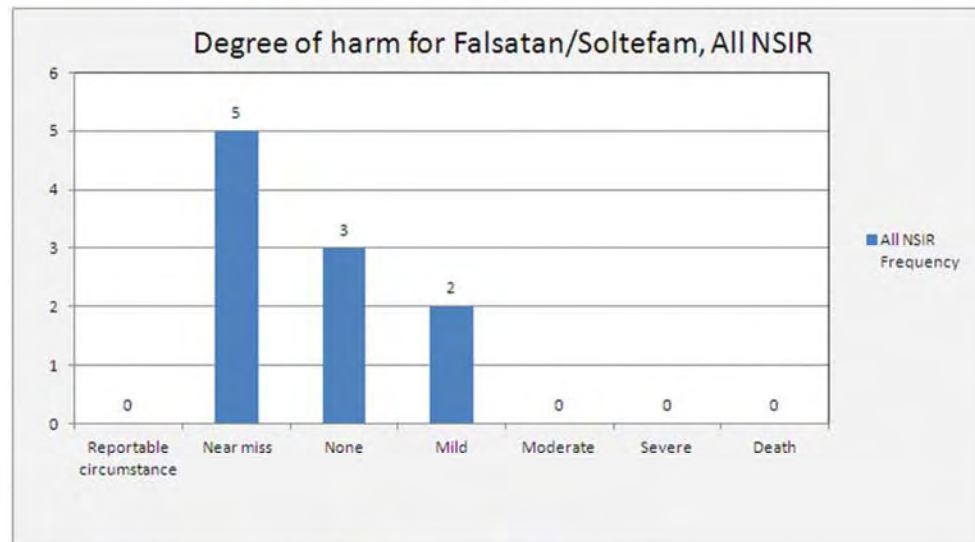
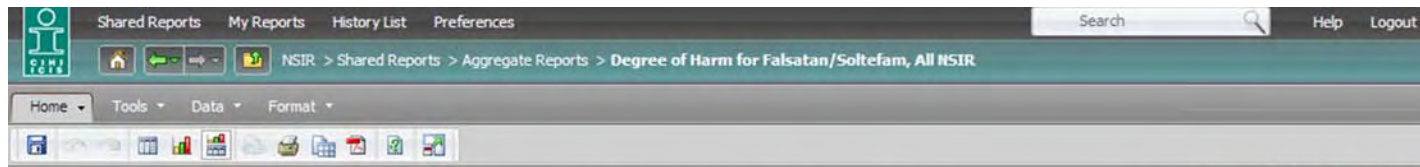
Analysis

- The types of analyses conducted can include individual report review and aggregate review.
- The focus is on identifying underlying issues.
- Health Canada becomes involved in analysis of reports involving product-related issues.

Analysis

- Searching of databases is an essential step in the analysis process.
- Incidents that occur in one jurisdiction have a high likelihood of recurrence elsewhere.
- A proactive approach is used to identify trends and emerging issues.

Sample NSIR Report



Data rows: 7 | Data columns: 1

Degree of Harm	All NSIR Metrics	All NSIR Frequency
Reportable circumstance		0
Near miss		5
None		3
Mild		2
Moderate		0
Severe		0
Death		0
Total		10



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Drugs and Health Products

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MedEffect™ Canada

Together we can improve health product safety

www.healthcanada.gc.ca/medeffect



Canada Vigilance Program

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. Post-market surveillance enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

The Canada Vigilance Program has collected reports of suspected adverse reactions since 1965. Adverse reaction reports are submitted by health professionals and consumers on a voluntary basis either directly to Health Canada or via Market Authorization Holders. The following health products marketed in Canada are collected by the program: prescription and non-prescription medications, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products and radiopharmaceuticals. The information collected by the program can be accessed through the [Canada Vigilance Online Database](#).

Quick Links

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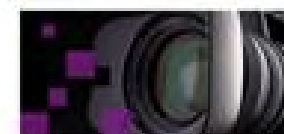
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NEWS



Watch the launch of the Global Patient Safety Alerts.

[Access Now](#)

Safe care . . . accepting no less.

Frontline healthcare providers and healthcare organizations around the world are looking for and developing solutions to patient safety incidents and challenges.

Global Patient Safety Alerts is an innovative information-sharing resource to help you prevent and mitigate patient safety incidents in your organization and help others succeed.

Just updated! Now you can search and browse over 650 patient safety incident advisories, alerts, and recommendations. Learn what works and share your own insights and solutions with healthcare providers, healthcare organizations, patients, and the public. We are continuously adding new alerts so check back often.

You'll also find customizable, evidence-based tools you can start using immediately to help you achieve your goals.

By asking, listening, and talking to one another, we can grow our own patient safety and quality initiatives and help others grow theirs. Join the conversation and get the solutions you need today.

Solutions Development

- Prevention strategies , as well as strategies to mitigate harm are developed.
- These strategies are dependent upon on the nature of the issue.
- Through CMIRPS, work is done at the local, regional, provincial/territorial, national and international level.

Sharing CMIRPS Learning

- ISMP Canada Safety Bulletins
- ISMP Canada SafeMedicationUse.ca
Newsletters and Alerts
- Health Canada “Dear Healthcare Provider”
letters
- CPSI Global Patient Safety Alerts
- ISMP Canada workshops, webinars, toolkits

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.



The Healthcare Insurance Reciprocal of Canada (HIROC) is a member owned expert provider of professional and general liability coverage and risk management support.

Volume 11, Number 4

ISMP Canada Safety Bulletin

May 27, 2011

Drug Name Alert: Potential for Confusion between Pradax and Plavix

ISMP Canada has received 3 incident reports from healthcare practitioners related to the brand names Plavix (clopidogrel) and Pradax (dabigatran etexilate). Two of these reports identified concerns about the potential for confusion between the brand names. The third report, received just recently, described a mix-up that reached a patient:

An otherwise healthy patient was scheduled for an endovascular coiling procedure to treat a brain aneurysm. Several days before the procedure, the neurosurgeon wrote a prescription for Plavix 150 mg po daily with acetylsalicylic acid (ASA) 325 mg po daily. The patient was to take these medications to prevent platelet aggregation and clot formation during, and as a result of, insertion of a foreign substance (the coils) into the vascular system.

The day before the scheduled procedure, the patient was admitted to the hospital as planned. Fortunately, the patient had remembered to bring all current medications to the hospital. During medication reconciliation, the pharmacist noticed that the patient was taking Pradax

Pradax (dabigatran etexilate) is an oral anticoagulant (direct thrombin inhibitor) that was initially approved in Canada in 2008 for the prevention of venous thromboembolic events in patients who have undergone elective total hip or knee replacement. An additional indication for the use of Pradax, the prevention of stroke and systemic embolism in patients with atrial fibrillation, was approved on October 26, 2010.²

As noted above, Plavix is indicated for patients for whom treatment with an anticoagulant is unsuitable. Because Pradax is an anticoagulant, it should not be given to such patients. A mix-up between Plavix and Pradax could have serious consequences. If a patient is supposed to receive Plavix, but Pradax is supplied (e.g., the prescription is written incorrectly or the wrong drug is dispensed) the patient will not experience the desired antiplatelet effect and could be at increased risk of bleeding. Similarly, if a patient is supposed to receive Pradax, but Plavix is supplied, the patient will not experience the desired anticoagulant effect.

Both Plavix and Pradax begin with the letter "P," so the 2 drugs may be stored in close proximity in medication

Help Prevent Medication Incidents

A component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

Volume 2, Issue 3

Alert

May 27, 2011

Alert: Beware of Potential Confusion between Pradax and Plavix!

ISMP Canada has received reports about confusion between the Canadian brand names of 2 drugs: Pradax (generic name dabigatran etexilate) and Plavix (generic name clopidogrel). The brand names Pradax and Plavix may look very similar when written by hand. The names can also sound similar when spoken aloud.

Both Pradax and Plavix are used to prevent unwanted blood clots, but they work in different ways and are used in different circumstances. Plavix keeps platelets (blood cells that are involved in the formation of clots) from sticking together. Pradax is an anticoagulant; it blocks one of the substances that cause blood to clot. Plavix is sometimes prescribed for patients who can't take anticoagulants, so a mix-up between these drugs could be serious.

In one incident, a patient needed a procedure to treat a brain aneurysm. The patient was supposed to take **Plavix** with Aspirin for several days before the procedure. There was a mix-up at the community pharmacy where the patient had the prescription filled, and the patient was given **Pradax** instead of Plavix. The patient took the Pradax capsules, along with the Aspirin, for several days before going to the hospital for the procedure. Fortunately, the patient remembered how important it is to bring all your medicines with you any time you go to a hospital for treatment. A pharmacist reviewed the medicines when the patient was admitted to the hospital, noticed the problem, and called the community pharmacy. The community pharmacist confirmed that the order for Plavix had been misinterpreted and that Pradax had been dispensed in error. The neurosurgeon was notified, and the procedure was postponed.

Health Canada Health Professional Communication



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Drugs and Health Products

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Maalox Multi Action (bismuth subsalicylate) - Confusion with Other Maalox Liquid Products - For Health Professionals

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the [alternate format help section](#).

(PDF Version - 58 K)

Contact: [Marketed Health Products Directorate](#)

The Health Products and Food Branch (HPFB) posts on the Health Canada Web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Novartis Consumer Health Canada Inc.** Contact the company for a copy of any references, attachments or enclosures.

Health Canada Endorsed Important Safety Information on Maalox Multi Action (bismuth subsalicylate)

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Health Canada Endorsed Important Safety Information on Maalox Multi Action

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Results for:concentrated electrolytes

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2009-10-01

[Hospital-Acquired Hyponatremia: Two Reports of Paediatric Deaths](#)

[Institute for Safe Medication Practices Canada Canada](#)[Topic](#) Medication

[Summary](#)

The Bulletin describes two incidents where paediatric patients developed hyponatremia associated with the intravenous administration of hypotonic solutions; one in a postsurgical setting and the other in a medical setting. Both incidents resulted in death. Acute hyponatremia is defined as a decline in serum sodium within a 48-hour period to less than 130 mmol/L. This abrupt change can lead to cerebral edema as a result of electrolyte-free water moving into the brain cells. Acute hyponatremia ca...

[Organization](#)[All](#)[Institute for Safe Medication Practices Canada](#)[National Center for Patient Safety \(Department of Veteran's Affairs - USA\)](#)[Queensland Health \(Australia\)](#)

2009-08-01

[Elevated serum magnesium in a premature infant receiving Total Parenteral Nutrition](#)

[Winnipeg Regional Health Authority \(Canada\) Canada](#)[Topic](#) Neonatal/Paediatric

[Summary](#)

An infant receiving total parenteral nutrition was found to have elevated serum magnesium resulting in intubation, ventilator support, prolonged admission and other treatments. After analysis of the TPN residue in the bags, it was suggested that the volumes added of calcium and magnesium may have been reversed however other explanations are possible as well. Mixing TPN, a task requiring intense concentration, is scheduled at the end of a day shift and in an area with many distractions. The infan...

Other Actions

- Consideration of a name change or label change
- Review of policies and procedures to prevent or mitigate risks
- Changes to Accreditation Canada standards or professional standards
- CPSI supports other related patient safety initiatives

Example of Packaging Change





Example of Changes to Standards

<http://www.ornac.ca/standards/>

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The Healthcare Insurance Reciprocal of Canada (HIROC) is a member owned expert provider of professional and general liability coverage and risk management support.

Volume 11, Number 6

ISMP Canada Safety Bulletin

September 30, 2011

Updated Operating Room Standards Include Strategies to Prevent Inadvertent Injection of Epinephrine Intended for Topical Use

Information published by the Institute for Safe Medication Practices Canada (ISMP Canada), and others has highlighted substitution errors involving the inadvertent injection of concentrated epinephrine (1 mg/mL) intended for topical application during elective outpatient ear, nose, and throat procedures.¹⁻⁷ In a collaborative effort to enhance the safety of epinephrine use, the Operating Room Nurses Association of Canada (ORNAC) worked with ISMP Canada to incorporate incident learning into its

A failure mode and effects analysis (FMEA) confirmed the importance of these additions to the standards (refer to the sidebar on page 2 of this bulletin for additional information).

ORNAC has taken a leading role on this issue and has set an example among national and international standard-setting organizations.

ISMP Canada continues to work with manufacturers and

Summary

- CMIRPS is a collaborative program that contributes information, tools and expertise to enhance the safety of the medication use system
- **Reporting** by healthcare professionals, consumers and patients contributes information that enables the identification of problems, analysis of information and sharing of solutions by CMIRPS
- Working together, we can prevent and reduce harmful medication incidents

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