

Medication Incidents – What Can We Learn from Coroner's Inquests?

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Ontario Hospital Pharmacy Management Seminar Deerhurst, Sunday, May 24, 2015

ISMP Canada

ISMP Canada is an independent not-forprofit organization dedicated to reducing preventable harm from medications.

Our goal is the creation of safe and reliable systems for managing medications in all healthcare environments.

www.ismp-canada.org





A Key Partner in the Canadian Medication Incident Reporting and Prevention System (CMIRPS)

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Advancing safe medication use

The Institute for Safe Medication Practices Canada is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.









Reporting and Prevention Systems



Medication Incident and Near Miss Reporting Programs for:

- Practitioners
- General Public SafeMedicationUse.ca

MOHLTC Supported Initiatives



Ontario Critical Incident Learning

- · Safe Use of Insulin Interventions
- Medication Safety Support Service (MSSS)
- Ontario Antimicrobial Stewardship Project
- Operating Room Medication Safety Checklist®
- . FMEA Report Reducing the Risk of Inadvertent Injection of Concentrated Epinephrine Intended for Topical Use
- · Multiple IV Infusions: Project | Webinar
- Safer Medication Use in Older Persons

Multi-Stakeholder Projects



Canadian Pharmaceutical Bar Coding Project



MyMedRec App- Keep track of your medicines and vaccines



Canadian Incident Analysis Framework



Consumers Can Help Prevent Harm from Opioid Use!

Upcoming ISMP Canada Events

Webinars Thursday, September 19, 2013 Wednesday, October 2, 2013 Tuesday, October 8, 2013

Development of a Guide to Support the Design of Safe Health Product Labels and Packages

The Risk of Look-Alike Arterial Blood Gas Syringes: A Blinded Experiment

Promoting the Safe Use of Insulin in Hospitals

Wednesday, September 18, 2013

This session is full. BPMH Training for Pharmacy Technicians - Toronto, ON

Request to be placed on the wait list of this session.

Thursday, September 26, 2013. Friday, September 27, 2013

Root Cause Analysis (RCA) Workshop for Pharmacists - Toronto, ON

Friday, September 27, 2013

Incident Analysis Framework Train-the Trainer Workshop For PSEP-Canada Trainers - Toronto, ON Proactive Risk Assessment in Pharmacy Practice using Failure Mode and Effects Analysis (FMEA) - Toronto, ON

Wednesday, October 9, 2013 Root Cause Analysis (RCA) Workshop for Nurses - Toronto, ON



SafeMedicationUse.ca





Help Prevent Harmful Medication Incidents

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

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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.



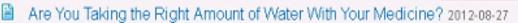
REPORT NOW

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

Sign up to receive the latest Alerts and Newsletters:







- Health Canada Endorsed Important Safety Information about potential device failure with Pulmicort Turbuhaler 2012-07-28
- Take Care with Medicine Patches 2012-07-04
- Health Canada Endorsed Important Safety Information on the Dangers
 Associated with the Use of Counterfeit Drugs 2012-06-22
- Preventing Harm from Drug Interactions: Consumers Can Play an Important Role 2012-06-14
- Check Labels Carefully When Selecting Gravol Products! 2012-05-04
- Consumer Catches Error Involving Similar Medicine Names 2012-05-01



ISMP Canada Safety Bulletins



Institute for Safe Medication Practices Canada REPORT MEDICATION INCIDENTS

Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

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Reporting and Preversion System
Systems cancellas de Melgretion et de prevention des Indidacts médicamentaus

ISMP Canada Safety Bulletin

Volume 14 - Issue 7 - July 30, 2014

Neuromuscular Blocking Agents: Sustaining Packaging Improvements over Time

Neuromuscular blocking agents, also known as paralyzing agents, are high-alert medications. They paralyze muscle function by blocking the connection between nerves and muscles. Notably, the muscles that are essential for breathing become paralyzed in patients who receive these medications-these patients need to be immediately ventilated. Serious injuries and deaths have occurred with substitution errors involving these drugs.14 Incidents involving inadvertent administration of neuromuscular blocking agents and recommendations for prevention of error have been highlighted in previous issues of the ISMP Canada Safety Bulletin. 1,2 The purpose of the current bulletin is to affirm the progress that has been made in the packaging and labelling of these drugs, in an effort to sustain key safety improvements.

Background

In 2006, ISMP Canada convened a meeting of representatives of Canadian manufacturers of neuromuscular blocking agents. The intent was to collaborate in identifying opportunities to reduce the

risk for accidental administration of a neuromuscular blocking agent because of a product mix-up.⁵

The pharmaceutical representatives agreed upon several ideal packaging and labelling features for neuromuscular blocking agents to help differentiate them from all other drugs:⁵

- red cap with white lettering: "Paralyzing Agent" or "Warning: Paralyzing Agent"
- red ferrule (metal seal) with white lettering: "Paralyzing Agent"
- red lettering on the product label: "Paralyzing Agent" or "Warning: Paralyzing Agent"
- peel-off label, using the colour scheme and content information recommended in standards for labels to be applied to prepared syringes, as set out by the Canadian Anesthesiologists' Society (CAS; www.cas.ca) and the American Society of Anesthesiologists (ASA; www.asahq.org)
- · space on the product label for application of a bar code

Figure 1. Examples of closures on vials of neuromuscular blocking agents currently available in Canada. Although the colour may vary (see "Note about Colour" on next page), all neuromuscular blocking agents currently available in Canada have a warning on the cap and/or ferrule.













ISMP Canada Safety Bulletin - www.ismp-canada.org/ISMPCSafetyBulletins.htm

1 of 7





Place patient-specific labels on the barrel of the insulin pen, not on the cap.

Use insulin cartridges only with an insulin pen. Do not use a needle and syringe to withdraw insulin from a cartridge.
 Use educational tools such as the ISMP Canada e-Learning module, along with

hands-on training, to educate healthcare providers on the potential risks associated with using these devices, as well as on best-practice techniques.



Use bulletin, in addition to

module, as an educational resource in your hospital's safety huddles or rounds

other tools such as the

insulin pen e-Learning

Presentation Outline

- Overview of death investigation systems in Canada
- Overview of ISMP Canada collaboration with provincial and territorial Offices of the Chief Coroner/Chief Medical Examiner
- Description of inquest process
- ISMP Canada involvement in death case reviews and inquests
- Lessons for Pharmacy leaders



Death Investigation Across Canada

- Every province and territory has a death investigation system
- Both coroner and medical examiner systems in Canada
 - Some jurisdictions have physician-based programs; others may or may not require a healthcare background
 - Focus is similar but coroner services may have a stronger preventive mandate



ISMP Canada Involvement with Offices of the Chief Coroner/Chief Medical Examiner

- 2004 Review of medication error associated deaths investigated by Ontario coroners – 32 cases reviewed
- 2006 and 2010 additional Ontario data collection projects
- 2012-13 National collaborative project with 4 provinces: NS, ON, QC, SK
 - 523 cases reviewed; 122 medication incidents abstracted for further analysis



Key Findings from 2012-13 Project

Table 1: Medication classes most commonly involved in incidents associated with death

Medication Class	No. (%) of Incidents *
Total no. of category I cases	115 (100%)
Opioids	54 (47%)
Psychotherapeutic agents	28 (24%)
Anticoagulants	24 (21%)
Cardiovascular agents	11 (10%)
Insulin	8 (7%)

^{*}Some incidents involved more than one medication class.

ISMP Canada Safety Bulletin. Deaths Associated with Medication Incidents. 2013; 13(8); http://www.ismp-canada.org/download/safetyBulletins/2013/ISMPCSB2013-08_DeathsAssociatedWithMedicationIncidents.pdf



Key Findings from 2012-13 Project

ISMP Canada Safety Bulletin.
Deaths Associated with
Medication Incidents. 2013;
13(8); http://www.ismp-canada.org/download/safetyBulletins/2013/ISMPCSB2013-08_DeathsAssociatedWithMedicationIncidents.pdf

Table 2: Medications most frequently involved in incidents associated with death

Medication	No. of Cases*
HYDROmorphone	19
Morphine	13
Warfarin	11
Fentanyl	8
Insulin	8
Oxycodone	7
Amitriptyline	4
Methadone	4
Acetylsalicylic acid	3
Moxifloxacin	3
Olanzapine	3
Potassium	3
Tissue plasminogen activator (tPA)	3

^{*}Some incidents involved more than one medication.



Checklist for Investigating Deaths Involving Medication Errors

Checklist for Investigating Deaths Involving Medication Errors

Incident Details:

- Detailed description of incident circumstances, including:
 - Name, dose, route of medication as ordered
 - Name, dose, route of medication administered
 - How the incident was discovered
- Copies of original prescriber's order(s)
- ☐ Copies of medication administration record(s), narcotic record sheet(s), if applicable
- Actual packaging and/ or photographs of medications involved
 - In the case of an incorrect medication administration, include the intended medication/ dose as well as the actual medication/ dose administered

Supporting Information for analysis:

- Physical environment
 - o Photographs of drug storage in patient care areas and/ or pharmacy
 - Other information related to physical environment that may aid in understanding the circumstances
- Context for activities related to incident:
 - Copies of progress notes (physicians as well as other disciplines as applicable)
 - Information provided by practitioners and others surrounding the circumstances (e.g., staffing, workload, interruptions, environment (e.g., poor lighting), communication challenges (e.g., language barriers), difficult technology, etc.)
- Recommendations/ corrective actions arising from review conducted by facility

The goal is to look beyond the "what happened" to understand why and how it happened. Look beyond the provider/ patient interface for underlying contributing factors in order to develop recommended solutions that will be system-based, rather than reliant solely on education and care and vigilance of individual practitioners.





Secure Portal for Case Summary Submission for Coroners and Medical Examiners



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Français

ISMP (US)

submit

Feedback

Shared Learning from Death Investigations				
This secure portal prov sharing lessons learned	ides coroners and medical examiners with a direct, secure connection to ISMP Canada for the purpose of from case data.			
	w data submitted to assess opportunities for sharing generalizable learning and actions recommended to frecurrence, in a de-identified way, e.g., through an ISMP Canada bulletin.			
	he only mandatory field; all other data fields are optional. ISMP Canada respects the wishes of the reporter to be included in publications.			
Canada's privacy policy	ed will be used by ISMP Canada in accordance with its privacy policies, practices and procedures. ISMP is available at: http://www.ismp-canada.org/privacy_policy.htm. ALL INFORMATION SUBMITTED WILL BEDENTIAL AND PROTECTED.			
not about the individua remove identifying info	iewing and analyzing the documents provided, ISMP Canada requires information about the incident, but all who was the subject of the incident or the facility (if applicable) where the incident occurred. Please rmation (e.g., decedent's name or date of birth, healthcare facility name, healthcare provider names) prior its. (Any identifiers inadvertently submitted will be removed by ISMP Canada.)			
	he information provided only for the purposes of its mandate; i.e., to identify risks in medication use optimal system safeguards, and advance safe medication practices. Nothing that links you or your office to be shared publicly.			
investigations. Our wor	appreciates your willingness to share information about medication incidents identified during death k with coroners and medical examiners identifies important underlying contributing factors to incidents and helps us to fulfil our mandate of advancing medication safety in all settings.			
Document* (Mandatory field)	Choose File no file selected			
Comments				
Drug(s) Involved				
	Add			
Email address				
Name				
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Organization				
Phone				
City				
10025#K				

Province Postal code



Office of the Chief Coroner for Ontario

"We speak for the dead to protect the living"



The Office of the Chief Coroner for Ontario (OCCO) investigates:

- All non-natural deaths (including deaths resulting from medical/medication error)
- Certain natural deaths
 - Sudden and unexpected
 - Concerns about care (family; healthcare providers; coroner)
 - Vulnerable populations (e.g., every 10th death in LTC)



OCCO (cont'd)

Coroner's investigation serves two main purposes:

- Investigative
 - Who died, when, where, how, and by what means
- Preventative
 - Make recommendations aimed at preventing future deaths in similar circumstances
 - Through inquests, death review committees, special reviews



OCCO/ISMP Canada Collaboration

- Data collection and analysis
 - Ontario codes specifically for medication error and adverse drug reactions
- Patient Safety Review Committee
- Sharing of learning from case reviews through ISMP Canada Safety Bulletins and Ontario Critical Incident Learning Bulletins



Patient Safety Review Committee

- Interdisciplinary committee created in 2005
- Assists the OCCO in the review of deaths relating to healthcare-related cases where system-based errors appear to be a major factor
 - Provides recommendations to relevant organizations and professional groups towards reducing the likelihood of future similar events
- Assists coroners in improving the investigation of deaths in which systembased errors appear to have occurred



Other Provinces

- Case reviews by referral or direct request
 - May or may not include site visit
- Have completed case reviews with coroner referral or involvement, including inquest support for:
 - YK, BC, SK, ON, NB, NS, PE
- Several case reviews have been adapted for sharing in bulletins



Inquest Process

Definition:

"An inquest is a public hearing where witnesses are called and evidence heard before 6 jury members. Inquests may be held to determine the facts and circumstances surrounding the death and to bring dangerous practices to light.... The inquest is fact finding, not fault finding. It is not a civil or criminal proceeding."

http://www.justice.gov.sk.ca/coroner-faq



When are inquests called?

- Custodial deaths (mandatory); unless expected of natural causes
- Other sudden, unexpected or unnatural deaths:
 - to determine the identity of the deceased and how, when, where and by what means he or she died;
 - to inform the public of the circumstances surrounding a death;
 - to make dangerous practices or conditions known and make recommendations to avoid preventable deaths; or
 - to educate the public about dangerous practices or conditions to avoid preventable deaths.



Inquest Preparation Process (Coroner Process)

- Preparation of formal report based on review of available documents, for example:
 - Coroner's case summary
 - Health record, including EMS, Rx files, previous admissions
 - Pathology reports, including medical autopsy, toxicology results
 - Police investigation/interview summaries with staff
 - Reports of other expert witnesses



Inquest Preparation Process (cont'd)

- Submission of report to Chief Coroner
- Detailed review of report and preparation for testimony with Coroner's counsel (crown attorney)



Inquest Proceedings

- Public event; media presence common
- Similar to a courtroom process
 - "Judge" is a Coroner
 - Jury of lay people
- Parties with "standing" can question witnesses, themselves or through legal representative
 - E.g., hospital, family
- Expert witnesses may be allowed to observe full proceedings; other witnesses typically sequestered until after they have testified



Inquest Proceedings (cont'd)

- At the conclusion of the inquest, the jury delivers a verdict, answering the following questions:
 - Name of the deceased
 - Date and time of death
 - Place of death
 - Cause of death
 - By what means: natural, accident, homicide, suicide, or undetermined



Inquest Recommendations

- Inquest juries may make recommendations (this is not required)
- Inquest recommendations are nonbinding; however can strongly influence system change



Ontario Inquest Summary (2012)

- 37 inquests were held
- 24% of the inquests conducted were discretionary
- 76% of the inquests conducted were mandatory (custody, construction and mining)
- 43% were custody
 - 56% of the custody inquests involved police custody
- 30% were construction
- 3% were mining
- 11% of the inquests resulted in no recommendations
- a total of 316 recommendations were made
- on average, 80% of the organizations asked to respond, did so
- on average, each inquest in 2012 lasted 6 days

Office of the Chief Coroner for Ontario. 2012 Report on Inquests, Executive Summary. Available from:



Ontario Inquest Summary 2012

Of the deaths inquested in 2012:

- 22% were natural
- 49% were accidental
- 13% were suicides
- 16% were homicides
- 0% were undetermined
- 100% of the construction inquests and mining inquests were accidental deaths

Office of the Chief Coroner for Ontario. 2012 Report on Inquests, Executive Summary. Available from:



Ontario Inquest Summary (2012)

According to the responses received regarding recommendations:

- 8% have been implemented
- 4.2% will be implemented
- 1.8% have had alternates implemented
- 0% will have alternates implemented
- 5.6% are under consideration
- 17.7% content or intent of recommendation already in place
- 0.3% have unresolved issues
- 0.4% were rejected with no specific reason given
- 1.3% were rejected due to flaws
- 0.4% were rejected due to lack of resources
- 43.3% did not apply to the agency assigned*
- 16.2% no response received
- 0.7% received responses that could not be evaluated

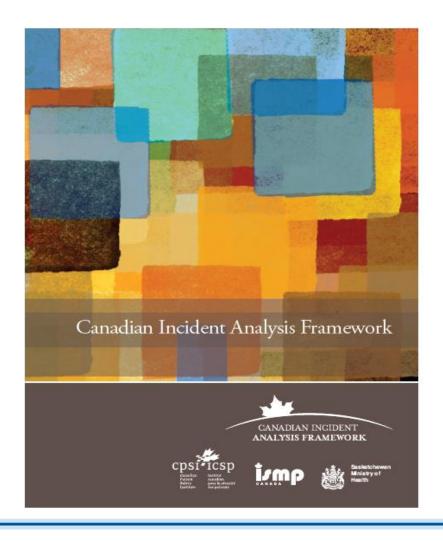
Office of the Chief Coroner for Ontario. 2012 Report on Inquests, Executive Summary. Available from:





How does ISMP Canada approach incident analysis for inquest cases?

- Canadian Incident Analysis Framework (2012)
 - CPSI, ISMP Canada, Saskatchewan Health, Patients for Patient Safety Canada, Paula Beard, Carolyn Hoffman, Micheline Ste Marie
- Systematic approach to incident analysis
- Applicable to all incident analyses





Foundational Principles

Errors occur at all levels of healthcare

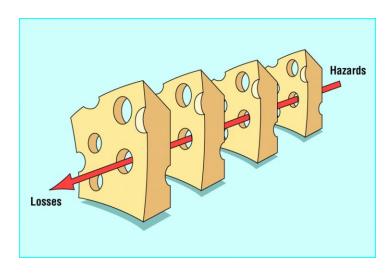
 All staff, even the most experienced and dedicated professionals can be involved in preventable adverse events

 Incidents result from a sequence of events and tend to fall in recurrent patterns regardless of the personnel involved



Systems Approach

Focus on improving the processes, systems, and environment in which people work rather than attempting only to improve individual skills and performance



Reason, J. (2000). Human error: models and management. *BMJ*, 320(7237): 768-770. Retrieved from:

http://www.bmj.com/cgi/content/full/320/7237/768



ISMP Canada Expert Witness Involvement in Inquests

- 2004
 - Potassium chloride administered direct IV instead of saline in acute care
- 2012
 - Incorrect opioid administration in long-term care
- 2014
 - Quetiapine toxicity in detention centre
 - Opioid-associated death in a small community hospital



2004 - Potassium Chloride (KCI)

- KCl administered direct IV instead of saline flush in a community hospital
- Jury verdict:

Cause of death: cardiac arrest, caused by the intravenous injection of concentrated potassium chloride

By what means: Accident



2004 - KCI - Jury Verdict (cont'd)

- 31 recommendations, including:
 - Complete removal of concentrated KCl from patient care areas in hospitals
 - Manufacturers' packaging format should be highly distinguishable from other drug products, using clear and obvious warning labels



2012 — Incorrect Opioid Administration in Long-Term Care

- Presumed administration of MS Contin 60 mg instead of prescribed propoxyphene 100 mg at bedtime
- ISMP Canada conducted site visit to long-term care home and pharmacy supplying the home in preparation for inquest



Incorrect Opioid Administration in Long-term Care (cont'd)

- Jury verdict:
 - Cause of death: active chronic bronchitis and acute aspiration pneumonia
 - Pathologist and toxicologist commented that the respiratory depressant effects of morphine could not be excluded as a factor contributing to the death.
 - By what means: jury opted to leave this question unanswered, which is an available option
 - 8 recommendations
 - Key focus on processes related to management of suspected errors



2014 — Quetiapine Toxicity

- Inmate found unresponsive in cell
 - Inquest mandatory for custodial deaths
- Toxicology and pathology suggested death related to combined toxicity of quetiapine, doxepin and amitriptyline
 - Only quetiapine had been prescribed
- ISMP Canada was asked to conduct a site visit and review processes to determine the potential for a medication error and present findings at inquest



2014 – Quetiapine (cont'd)

• Jury verdict:

- Cause of death: combined toxicity of quetiapine, doxepin and amitriptyline
- By what means: suicide
- 7 recommendations, including:
 - Continued vigilance to identify and reduce "cheeking", hoarding and diversion of drugs by inmates
 - Avoidance of medication administration during lockdown
 - Review of Medication Dispensing System at this and other detention centres



2014 — Opioid-Associated Death in a Small Community Hospital

- Patient admitted for management of acute pain subsequent to an injury 2 months before admission
 - Prior history of back surgery and some regular opioid use (estimated at 4 tablets of Percocet daily)
 - Opioids were increased subsequent to the injury and increased further after admission
 - Key concerns were related to opioid selection and dose titration, and monitoring procedures
 - The day prior to death the patient was estimated to be receiving the equivalent of 400 mg of oral morphine



2014 — Opioid Associated Death (cont'd)

- Jury verdict:
 - Cause of death: mixed drug toxicity
 - Manner of death: accident
 - 6 recommendations, 2 related to ISMP Canada's review:
 - That the hospital implement all of the recommendations made by ISMP Canada
 - That the Chief Coroner and ISMP Canada collaborate to share the learning in an ISMP Canada Safety Bulletin



Lessons for Pharmacy Leaders

- Deaths represent the most serious potential outcome of a medication error
- Fortunately, deaths are infrequent, but they are not rare
 - ISMP Canada database of over 72,000 incidents includes nearly 300 deaths and 3000 harm incidents
 - Each harm event involves real people and families whose lives are forever changed



What can Pharmacy Leaders Do?

Continue to:

- Support incident reporting and analysis processes, including near misses
- Promote the need for high leverage changes to medication management systems to decrease error potential in systems
- Promote open and transparent communication with patients and families when errors occur



Personal Reflections

- Inquests, while intended to be fact-finding, can in fact be very adversarial
 - Parties with standing can have very different goals for the outcome
 - While not a criminal proceeding, courtroom process is highly intimidating
- Should be better ways for families to feel heard and get changes made for improved care in the future



The ultimate purpose of a critical incident investigation is always to prevent similar occurrences and thus improve safety.

Woloshynowych, M. Rogers, S., Taylor-Adams, S., and Vincent, C. *The investigation and analysis of critical incidents and adverse events in healthcare*. Health Technology Assessment 2005. Vol 9:19.



We encourage you to report medication incidents

ISMP Canada:

Practitioner Reporting https://www.ismp-canada.org/err_report.htm



Consumer Reporting

www.safemedicationuse.ca/



Canadian Institute for Health Information (CIHI) -- National System of Incident Reporting (NSIR)

http://www.cihi.ca/CIHI-extportal/pdf/internet/NSIR_PRO GRAM_OVERVIEW_EN



Upcoming ISMP Canada Education Events

Event	Date
Going beyond the numbers: A novel approach to understanding patient safety from medication incidents (*NEW)	June 3 rd (1 day)
Resolving Drug-Drug Interactions: A Guide for Community Pharmacies to Reduce Potential Hospitalizations (*NEW)	June 10 th and 18 th (2 hours – 3 timeslots)
Medication Safety for Pharmacy Practice: Incident Analysis and Prospective Risk Assessment	June 11 th -12 th ; November 5 th -6 th (1.5 days)
BPMH Training for Pharmacy Technicians	October 22 nd





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