The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent Canadian nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.



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"Paralyzing" Mix-ups in the Operating Room: Opportunity to Improve Safety with Neuromuscular Blockers

ISMP Canada Safety Bulletin

Medications used in the Operating Room (OR) are often prescribed, prepared and administered by the same individual and this can limit the opportunities for detection of an error before it reaches the patient.¹ Even when a second practitioner in the operating room administers a medication, it is often in response to a verbal order, and verbal orders are known to increase potential for error.² The inadvertent administration of a neuromuscular blocker to a non-intubated patient has been reported in the past; in several cases the outcome was catastrophic. ^{3 4 5 6} The majority of reports describe errors with neuromuscular blockers in patient care areas that are outside of the OR.

ISMP Canada has received four reports of inadvertent administration of a neuromuscular blocker to non-intubated patients in the OR. In all cases, the ensuing respiratory compromise was treated without subsequent complication. Information about these incidents was voluntarily provided to ISMP Canada to develop and promote recommendations for prevention. To our knowledge there have been no case reports in the medical literature describing such errors in the OR setting. ⁷ However, correspondence with anesthesiologists suggests that substitution errors in the OR involving neuromuscular blocking agents are not as uncommon as previously believed.

The first report describes the sudden development of respiratory compromise in a patient undergoing a minor surgical procedure requiring only local anesthesia and sedation. Immediate interventions included intubation and ventilatory support. The patient required ventilation for approximately 10 minutes. The anesthesiologist later surmised that the neuromuscular blocker, atracurium, might have been administered to the patient instead of the intended midazolam. That the atracurium and midzolam vials were both 10 mL in size and located adjacent to each other in the anesthesia drug cart supports the possibility that such an error could have occurred.

Contributing factors to the error as identified by the hospital included (i) the proximity of midazolam and atracurium vials in the anesthesia drug cart; (ii) the substitution of rocuronium (a commonly used neuromuscular blocker in a 5 mL vial) with atracurium (10 mL vial) in the anesthesia drug cart due to a national (manufacturer) shortage of rocuronium. [Practitioners at this hospital were presumably accustomed to having the neuromuscular blocker in the smaller 5 mL vial and the midazolam in a 10 mL vial. Such familiarity can lead to assumptions that can facilitate human error when one 'sees' what the mind 'expects' to see – this phenomenon is described as *confirmation bias*].

The second error report describes the inadvertent administration of rocuronium from an unlabelled pre-filled syringe located on the top of an anesthesia drug cart. The intended drug was a sedative. The patient was successfully resuscitated after suffering a respiratory arrest.

In a third report a patient developed cardiac dysrhythmias and respiratory compromise as he was being prepared for an elective procedure under local anesthesia with sedation. It was discovered that 1mL (10 mg) of rocuronium had been accidentally administered instead of midazolam. The patient was intubated and treated with a

cholinesterase inhibitor (i.e. a neuromuscular blocker antagonist – commonly known as muscle relaxant "reversal"). The surgery was rescheduled.

The fourth error report is similar to the above reports. After receiving medications intended to provide (conscious) sedation anesthesia, a patient appeared "floppy" and exhibited signs of neuromuscular weakness. (In anesthesiology, "floppy" is used to describe the appearance of emerging / conscious patients who still have (pharmacologically) impaired function at their neuromuscular junction. Clinically the patients appear weak and their purposeful attempts at movement cause them to appear like "fish out of water"). It was discovered that a neuromuscular blocker had been inadvertently administered instead of the intended midazolam.

In addition, ISMP Canada has received one report of a 'near miss' with a neuromuscular blocker in the OR. An anesthesia resident prepared one syringe containing fentanyl and a second syringe containing rocuronium. The attending anesthesiologist discovered that both syringes had been labelled as containing fentanyl and the syringes were therefore discarded and new syringes prepared.

The following recommendations for preventing error-induced injuries with neuromuscular blockers in the OR have been developed with input from several anesthesiologists:

- 1. When preparing syringes of medication for use during anesthesia label all syringes even when only one product is needed:
 - Identify the desired medication vial required for a procedure and withdraw the desired volume into a syringe. Leave the vial on the workspace and immediately label the syringe barrel. Do not label the needle cap or plunger.
 - Consider using standard printed labels available from medical suppliers. Some anesthesiologists securely affix each label with clear tape as an additional precaution to prevent the labels from falling off the syringe. See also number 5 below.
 - Place the label around the syringe barrel so that the label can be seen regardless of orientation (this may require a second label)
 - Discard the (empty) vial only when the preceding has been completed. [It is noted that some anesthesiologists advocate for keeping a small container with used vials on the workspace, until completion of surgery, in the event that a verification

A medication safety collaborative has been established between the Canadian Anesthesiologists Society (CAS) and ISMP Canada. One of the identified goals is to develop a specific medication safety selfassessment tool for operating rooms. The project will be preceded by a review of selected hospital operating rooms for the purpose of identifying the drug safety issues amenable to system improvements. Consultants from CAS, ISMP Canada and ISMP US will participate in this initiative. process is needed].

- Do not keep the syringe inserted into the vial as a means of identification.
- Place the labelled syringe in a designated location to avoid cluttering the workspace but still allow convenient access.
- Repeat when additional medications are required.
- 2. Before starting a procedure verify that all syringes on the workspace are required. Remove any syringes (e.g. from a previous procedure) not required.
- 3. Standardize medications kept as inventory in the OR.
- 4. Conduct regular reviews of all medication storage areas within the OR. Optimize storage locations with clearly labelled and uncluttered storage spaces. Verify that quantities on hand reflect usage and that drugs no longer used are removed from inventory areas.
- 5. When there is a change in product because of a new supplier contract or because of a product backorder it is imperative that point of care communication be provided by pharmacy. This is especially important in settings such as the OR where several medications are routinely administered on a recurrent basis. Unexpected changes in packaging or concentration can be a set-up for human error. When new products are added to existing cabinets, carts or trays they should be provided in a "Ziplock" bag with a label communicating the change. In addition, the Department of Anesthesia should receive formal written notification via memorandum.
- 6. Hospitals should check to see if there is a problem with the labels (from medical suppliers) adhering to syringes. In our discussions with anesthesiologists it was discovered that there have been complaints forwarded to label suppliers related to the efficacy of the label adhesive. It has also been surmised that changes in

composition of the plastic in the syringes have rendered previously adequate label adhesive ineffective. Hospitals are encouraged to review this issue. If a problem is confirmed options include considering an alternate label vendor or requesting that the vendor improve the label adhesive. In the interim practitioners should consider reinforcing labels with clear tape.

ISMP Canada has contacted Health Canada requesting the coordination of a meeting with the pharmaceutical industry to discuss improvements in the packaging and labelling of neuromuscular blocking agents. Suggested changes include packaging these agents in vials with a closure system that is coloured in "anesthesia red" (Pantone Red 811). Both the cap and overseal must state "**Warning: Paralyzing Agent**" or "**Paralyzing Agent**" depending on the size of container. The overseal should also be transparent to allow visualization of the warning label. If packaged in ampoules, there must be "anesthesia red" coloured bands on the neck.⁶

One of the other problems identified through discussions with anesthesiologists is that the product labels on the containers themselves are often difficult to read (e.g. silk screen printing on glass ampoules or a manufacturer name in larger font than the drug name). ISMP Canada has worked in collaboration with the Canadian Standards Association (CSA), the Canadian Anesthesiologists' Society and the Canadian Society of Hospital Pharmacists to develop guidelines for pharmaceutical manufacturers in the labelling of parenteral products. Efforts have been made to have these guidelines (available from CSA) referenced by Health Canada.

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

¹ ISMP Medication Safety Alert! March 6, 2002. Cutting errors out of the operating room.

² ISMP Medication Safety Alert! January 24, 2001. Instilling a measure of safety into those "whispering down the lane" verbal orders. Available at: <u>http://www.ismp.org/msaarticles/verbalorders.html</u>. Accessed July 25, 2004.

³ ISMP Medication Safety Alert! December 18, 2002. Safety Briefs: Warning! Prevent mix-ups between vaccines and neuromuscular blockers.

⁴ ISMP Canada Safety Bulletin. December 2002. Neuromuscular Blocking Agents - Time for Action.

⁵ ISMP Medication Safety Alert! May 1, 2002. Safety Briefs, p.1.

⁶ ISMP Medication Safety Alert! Near fatal pediatric accident should force re-assessment of a common cost-cutting measure. August 25, 1999. Available at: http://www.ismp.org/msaarticles/nearfatal.html. Accessed on July 25, 2004.

⁷ Medline search (1966-2004) and Embase search (1980-2004).

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

To report a medication error to ISMP Canada: (i) visit our website <u>www.ismp-canada.org</u> or (ii) email us at info@ismp-canada.org or (iii) phone us at 416-480-4099. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.