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.

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

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Infusion Pump Project: Survey Results and Time for Action

Infusion pump problems are a current subject of concern in Canada and in many other countries, including the United States (US) and the United Kingdom (UK). The US Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database contains hundreds of reports of infusion pump problems.[1] As noted in the July 2003 ISMP Canada Safety Bulletin, the US Joint Commission on Accreditation of Healthcare Organizations (JCAHO) identified the improvement of infusion pump safety as one of their national patient safety goals for two consecutive years.[2] In a recent UK study reviewing 6770 medical device incidents which were reported between the years 1990 to 2000, infusion/transfusion issues accounted for 36% of the incidents.[3] An investigation of 1,495 incidents directly related to infusion pumps revealed that in 53% of cases there was no fault found with the device and that the user error rate was nearly three times higher with infusion pumps than with other medical devices.[3,4,5] ISMP Canada has received more than 100 error reports citing infusion devices as a contributing factor to medication errors. Several of the reports describe some level of patient harm, for example:

- Heparin infused at a rate of 500 mL over one hour due to incorrect entry of the volume to be infused as the infusion rate.
- Neonatal TPN infused at 33.9 mL/h instead of 3.9 mL/h for one hour.
- Fentanyl PCA infusion inadvertently shut off for 24 hours.

ISMP Canada undertook a national survey on infusion pump use in March, 2003. The Infusion Pump Survey was developed by ISMP Canada in collaboration with the Canadian Healthcare Association, Health Canada, Health Care Insurance Reciprocal of Canada (HIROC) and University of Toronto researchers. The survey was available in both French and English and had the following objectives:

1. Explore the existing level of infusion pump problems in Canadian hospitals.
2. Obtain data on pump problems experienced in Canadian hospitals.
3. Prioritize infusion pump issues.
4. Develop strategies for safer infusion pump use – related to both equipment and practice.

Responses were received from 340 hospital sites across the country, including both community and teaching hospitals. Information was provided on a number of aspects of infusion pump use, including qualitative data identifying a variety of user concerns.

Seventy-five percent of responding hospitals reported infusion pump problems. A break-down of the responses by provinces is shown in Figure 1.

The majority of reporting hospitals have limited the number of infusion pumps they use, with 70% of hospitals using 1-5 different pump models in their facilities and 20% reporting use of 6-10 pump models.

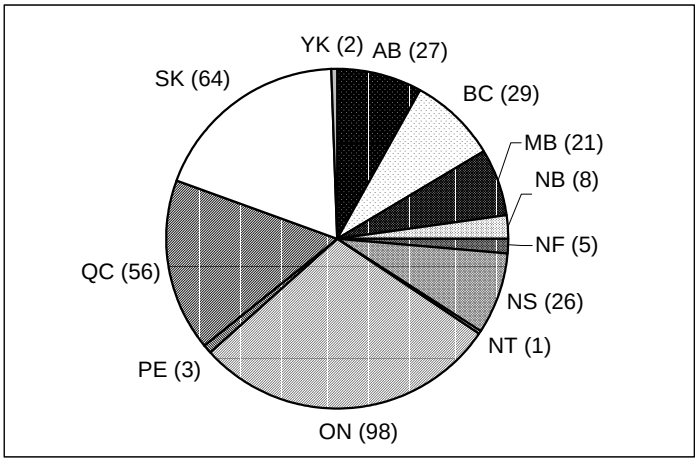

Figure 1. Number of hospital respondents by province (n=340).

The top five major categories of incidents identified by survey respondents are listed in Table 1 below. Many hospitals reported incidents in multiple categories.

Table 1. Top five major categories of incidents.

Category	Number	Percentage*
Incorrect Flow Rate	197	58%
Free Flow Errors	160	47%
Air Sensor Errors	161	47%
Overdose Errors	121	36%
Others	78	23%

* Percentages are based on the total number of respondents.

Table 2 provides some examples of specific incidents within each category. (Not all respondents provided this type of qualitative information. The examples are meant to illustrate some of the pump issues that were also reported within these headings in a free text format.)

Approximately one-half of the respondents reported a double check system for pump use. Heparin, insulin and narcotics were the medications most frequently cited as requiring double checks. The patient services most commonly using double checks were surgery, pediatrics/neonates, palliative care and critical care. In addition, 192 hospitals reported using a tamper-proof feature but a number of respondents commented that they wanted to see these features improved by the manufacturer, as patients could easily learn the feature from observing nurses.

Table 2. Examples of infusion pump incidents, in no particular order.

Incorrect Flow Rate Errors	Free Flow Errors	Air Sensor Errors	Overdose Errors	Other
Flow rate incorrectly set (see also *Overdose Errors*)	Pump/tubing does not have free flow safety mechanism.	False air in line alarm (e.g. when running blood or blood products).	Pump/tubing does not have free flow safety mechanism.	Mounting bracket failure caused pump to fall from IV pole.
Software error causing spontaneous change in rate.	Patient initiated.	Pump/alarm failed to detect air in line (e.g. faulty air sensor).	Patient/family gave extra doses (includes pumps with lock-out features).	Secondary IV mixing into primary despite back check valve.
Primary infusing instead of secondary line.	Tubing not correctly positioned inside pumping mechanism.	Tubing improperly placed in air sensor.	Pump did not detect correct syringe size.	Battery charge is not lasting.
Pump stopped/shut itself off (e.g. battery failure without alarm, computer lock up, fluid ingress into pump mechanism).	Door of pump not closed/ lever lock not engaged.	Tubing becomes kinked after 24 hours and starts to cause air alarm to ring.	Flow rate incorrectly set (e.g. confusion with multiple lines/pumps, between epidural and IV, pump programmed in mL/minute instead of mL/hour).	Amount administered greater than amount programmed.
Damaged pumping mechanism.			Electromagnetic/ electrostatic interference.	Display failures.

The survey respondents also provided suggestions for infusion pump design improvements. The following were the most requested features:

- On screen programming instructions,
- Protocol programming,
- Ability to program clinical maximum/minimum drug concentrations or dosing parameters,
- Clarity of display, and
- Ability to program primary vs. secondary infusion rates.

Only 7% of hospitals responded that they had reported a past problem to Health Canada; 42% had reported a problem to the pump manufacturer. Ninety-two percent of hospitals indicated that they would be willing to report future problems to ISMP Canada. Hospitals are encouraged to report infusion pump problems to Health Canada at 1-800-267-9675. Errors related to infusion pumps can also be reported to ISMP Canada for information sharing and learning.

ISMP Canada continues to seek resources to undertake more detailed analyses of infusion pump issues and begin to develop national safety strategies. In the interim, hospitals can consider implementing the following:

- Ensure that general-use infusion pump and PCA pumps are equipped with free-flow protection mechanism.
- Consider the use of smart pumps with safety features such as maximum dose/rate limit programming.
- Conduct a failure mode and effects analysis (FMEA) when acquiring new pumps, as well as for assessing pumps in current use.
- Limit the number of pump makes and models within an organization.
- Provide readily available and clear pump use instructions, using a safety checklist.[6]
- Implement "independent" double checks for high-alert drugs.[7,8]
- Provide comprehensive training on use of new pumps to all healthcare staff, including physicians.

References:

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6. ISMP Medication Safety Alert! Vol 8, Issue 15, July 24, 2003
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8. ISMP Medication Safety Alert! Vol 8, Issue 25, December 18, 2003.

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 www.ismp-canada.org 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.