



CANADIAN ASSOCIATION OF PAEDIATRIC HEALTH CENTRES
ASSOCIATION CANADIENNE DES CENTRES DE SANTÉ PÉDIATRIQUES



Health
Canada

Santé
Canada

Health Canada & Canadian Association of Paediatric Health Centres (CAPHC)

Patient Safety Workshop

June 14th, 2003
Calgary, Alberta

Proceedings Paper

Executive Summary

Background:

Unintentional strangulation in children is a widely recognized risk among healthcare providers, as a result of the unique vulnerability of this population. On July 30, 2002, a “Notice to Hospitals”, was issued by Health Canada that outlined a number of guidelines to improve patient safety regarding the use of IV tubing and monitor leads. While CAPHC and its members strongly support Health Canada’s commitment toward establishing optimal patient safety standards, concerns were raised by healthcare providers from across the country regarding the ability to carry out the recommendations, as outlined in the July 2002 directive.

Following a consultative process between Health Canada and members of CAPHC, a one day workshop in conjunction with CAPHC’s annual meeting was held to engage key stakeholders from across the country to address important issues surrounding patient safety.

Objective of the Patient Safety Workshop:

- to bring together representatives from Government, Children’s Hospitals/ Health Centres (paediatricians, family physicians, nursing personnel, administrators), family advisory representatives and other interested stakeholders;
- to develop a better understanding of the risk of strangulation of infants by IV tubing and monitor leads and to develop a consensus document to address common concerns regarding the “Notice to Hospitals” issued on July 30, 2002.

Workshop Proceedings:

To ensure broad dissemination and subsequent feedback from stakeholders nation-wide, CAPHC agreed to:

- Produce a comprehensive proceedings document that summarizes the workshop content and recommendations.
- Disseminate the conference proceedings through our Association’s multi-disciplinary child health network.

About the Canadian Association of Paediatric Health Centres (CAPHC):

Recently re-named, CAPHC was founded in 1968 as the Canadian Association of Paediatric Hospitals. CAPHC is a national, not-for-profit, organization whose members are multi-disciplinary health professionals that provide care for children, youth and families within community, regional and tertiary/quaternary health care facilities, rehabilitation centres and community home care services. CAPHC is affiliated with the sixteen health sciences centres in Canada providing linkages to clinical care, education and research.

Promoting best practices and optimizing resources are shared goals of our members and of all paediatric health care facilities nationwide. CAPHC is committed to supporting its members by promoting, facilitating and advocating for improved research, ultimately aimed at establishing national health service delivery guidelines for children and youth supported by evidence based data.

Supporting Information

Attached to this report are the following:

- Agenda of the Patient Safety Workshop held on June 14th, 2003.
- The original Health Canada Notice to Hospitals, dated July 30th, 2002.
- The suggestions for revision to the original Health Canada Notice to Hospitals.
- Discussion notes from the assembled group and expert speakers from the workshop.
- Future directions for desired outcomes of the Patient Safety Workshop.
- Supporting contextual material.

General inquires regarding this document should be addressed to:

Elaine Orrbine
Chief Executive Officer
Canadian Association of Paediatric Health Centres (CAPHC)
Association Canadienne Des Centres De Santé Pediatriques(ACCSP)
401 Smyth Rd.
Ottawa, Ontario
K1H 8L1
613-738-4164
fax: 613-738-3247
email: eorrbine@caphc.org
web: <http://www.caphc.org>

Acknowledgement:

These proceedings summarize the recommendations and consensus generated during the Patient Safety Workshop held on June 14, 2003 in conjunction with CAPHC's 2003 annual meeting, at the Calgary Hyatt Regency Hotel. The strength and positive outcome of the workshop is the result of a committed partnership between Health Canada and the members of the Canadian Association of Paediatric Health Centres.

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Introduction - Objectives and Context

As part of a consultative and collaborative forum, the Patient Safety Workshop was designed to address the challenges of ensuring patient safety for this vulnerable population at risk. The workshop engaged multidisciplinary child and youth health professionals and health policy experts (*Appendix A*) from across Canada and was organized with several key objectives in mind:

- To acknowledge and link common goals and priorities for patient safety.
- To develop a framework for continued national partnerships and communication around patient safety issues.
- To respond to Health Canada's Notice to Hospitals dated July 30th, 2002 regarding the Risk of Strangulation of Infants by IV Tubing and Monitor Leads.

Setting the Context- Expert Speakers

To set the context for the day several expert speakers were called on to share information with the assembled membership. Workshop speakers included:

- Dr. Jim King, Director of Paediatrics, *Children's Hospital of Eastern Ontario (Keynote speaker)*
- Barbara Brady-Fryer, RN, PhD (candidate), *Patient Care Director, Child Health, Stollery Children's Hospital and Royal Alexandra Hospital, Edmonton*
- Dr. Fred Lapner, *General & Restorative Devices Section, Health Canada*
- Dr. Philip Neufeld, *Therapeutic Products Directorate, Health Canada.*

Dr. Jim King, Keynote Speaker **Pediatric Injury- Bridging the Gap**

Dr. King spoke of the need to build a safer health system. A system founded on the basis that safety should always be the priority, particularly where children are involved, as they present a unique risk that needs to be protected.

Our health system should redefine how we look at safety, moving away from the concept of *medical error* and instead seeking answers regarding *systems failures*. Focusing on systems failures would have several positive outcomes;

- Using the concept of error limits our scope when looking for answers and solutions.
- Error often focuses on an individual as opposed to a system thereby taking responsibility away from an organization to implement revised safety measures.
- Error creates a climate where healthcare professionals may be less likely to report near misses as there are individual consequences to consider.
- Error review presents us with a limited view of safety, systems failure review asks us to look at an issue holistically and seek improved practices.
- Error review is focused on blame, systems failure review is focused on improvement.

When we start to accept that medical error is not the most effective way to review and then improve, we can begin to see that injuries are a disease. Injuries are not accidental, which implies that nothing can be done to improve the randomness of the event. Injuries are predictable, with many risk factors being identifiable. If an organization can believe this then injuries are also preventable.

Healthcare institutions can move toward an injury control model by adapting the following steps: (modified from Tugwell P et al, 1985)

Define the Injury Burden

- How many?
- How often?
- Create systems where employees report near misses.

Identify the Likely Causes

- Why is this happening?
- What are the repeatable factors?

Evaluate Efficacy of Interventions

- Will it work in a small control group?

Evaluate Effectiveness

- Where can the new intervention work throughout the organization?

Evaluate Efficiency

- What factors will contribute to the long term success of this intervention?

Monitor Policy and Practice

- Do system policies and practices support the ongoing success of the intervention?

An improvement in patient safety can only take place if leadership is shown around the issue. Pediatric healthcare professionals are uniquely situated to

address the risk and should work towards a model of systems improvement at both individual and organizational levels.

In *redefining the unacceptable*, patient safety becomes an issue all stakeholders take ownership over.

(For further information Dr. King's presentation slides are provided in the appendix).

Barbara Brady-Fryer, RN, PhD (candidate)
Strangulation with Intravenous Tubing: A Sentinel Event (Case Study)

Barbara Brady-Fryer presented a case study in unintentional infant strangulation with intravenous tubing. *(For case details see Pediatrics Vol. 111 No. 6 June 2003, Strangulation With Intravenous Tubing: A Previously Undescribed Adverse Advent in Children, attached in appendix).*

In speaking to this recently published article, Barbara Brady-Fryer outlined the two known cases of unintentional IV tubing strangulation. The two cases involved infants who became entangled in the IV tubing while not under the direct supervision of parent or healthcare professional.

In the first case, an 11-month-old boy was hospitalized after a diagnosis of pneumonia and dehydration. The child became entangled in IV tubing and was found with the tubing wrapped three times around his neck. The child was resuscitated, but suffered irreversible brain damage. With the parent's agreement, life support was discontinued.

In the second case, an 8.5 month-old boy receiving IV antibiotics for an infection was discovered by a nurse with IV tubing wrapped tightly around his neck. The boy recovered with no sequelae after being resuscitated.

Ms. Brady-Fryer went on to share how other organizations can learn from Stollery Children's Hospital response to such an event. She spoke of the need for a coordinated immediate response, the identification of underlying causes, the development of effective interventions such as risk surveillance and policy to guide practice in response to assessed risk.

Coordination, consistency, and a sustained effort are of the utmost importance if all the factors are to be assessed thoroughly. By improving the immediate and long term response we improve the likelihood of avoiding the system failure again. Immediate activities should include:

- The collection and documentation of basic information
- Support for family and employees
- A prepared and coordinated response to media requests

- Timely communication with internal and external stakeholder groups to appraise them of the event and the risk
- Communication with the Medical Examiner as required

Identifying the underlying causes from a systems failure point of view and not an individual error context is extremely important to avoid assigning blame and to ensure committed interdisciplinary participation in the effort to identify causes and solutions. Stollery Children's Hospital immediately established a Task Force whose members were charged with the mandate to answer the following questions:

- What were the contextual factors around the event? What were staffing levels like? Was there something different about the equipment, room or crib the infant was in? etc.
- Was there equipment failure? Did alarms function as expected?
- Was there a failure to follow standard practices and procedures?
- Were there barriers to or a lack of appropriate communication?
- Is there evidence of other events of this nature? Current literature? Other unreported cases?

The Task Force found that it had to be innovative in its approach, as evidence of others hospitals having gone through an event similar to this was not available. Systematic analysis of the events, voluntary and mandatory reporting, benchmarking of standard practices in other hospitals, a literature search for reports of similar incidents (for which they found nothing) and internal data collection of "entanglement incident" across the hospital for a 3 month period were the components of the comprehensive approach taken by the Task Force.

Next steps were the development of trial strategies to reduce/manage risks. Some of these strategies proved effective while others were flawed and therefore not implemented. Strategies included:

- Reducing IV use where appropriate (e.g. choosing oral vs. intravenous rehydration)
- Use of restraints for patients with IVs, (rejected as not practical, and potentially unsafe)
- In-house engineering to produce modified equipment, the length of tubing, the design of clamps, etc.
- Evaluating pump technology
- Preventing IV tubing from "wrapping" by encasing in plastic sleeve, (implemented as best possible preventative measure currently available)
- Measures to individualize care of patients with IV s written into hospital policy.
- Publication of case study/recommendations in the professional literature

Ms. Brady-Fryer recommended that in order to prevent this kind of tragic event from happening again and to put prevention practices for the future in place

organizations must show leadership and lead a sustained effort to identify solutions. The work done by the Task Force to date has spanned more than three years.

(For further information Ms. Brady-Fryer's presentation slides are provided in the appendix).

Dr. Fred Lapner
Medical Devices Regulations, Pre-Market Considerations

Dr. Fred Lapner, Health Canada, introduced the assembled group to the process of Health Canada's regulations surrounding medical devices and their pre-market considerations.

Health Canada's medical devices regulations have many general requirements for manufacturers of medical devices. These include:

- Safety and effectiveness requirements
- Labelling requirements
- The application for a medical device license for each product.

It is the role of the Health Canada's Medical Devices Regulations division to determine if new/amended device license applications meet the safety and effectiveness requirements of Canada's guidelines.

This system ensures that medical devices on the market are safe for patient use within healthcare settings across Canada.

(For further information Dr. Lapeer's presentation slides are provided in the appendix).

Dr. Philip D. Neufeld
Medical Devices Bureau, Post-Market Surveillance of Medical Devices

Dr. Philip D. Neufeld outlined the role of Health Canada's Medical Devices Bureau in the post market surveillance of medical devices. By law in Canada manufacturers are required to report serious incidents involving medical devices to Health Canada. "Serious incidents" are defined as those;

- Related to device failure, malfunction or labelling deficiency
- Or has led to death of a patient, or serious deterioration in health or could do so if it were to recur.

Dr. Neufeld outlined that while this is not a fool-proof system of questioning it does produce broad-based reporting. The Medical Devices Bureau, after a report

is submitted by a manufacturer, would then monitor the manufacturer's corrective action making certain that the product error is corrected.

Voluntary reporting also exists in this system, whereby hospitals can report incidents. These incidents are then catalogued in Health Canada's MDS database. The database currently has over 23,000 records, 10,000 incident reports and is searchable by manufacturer, device trade name, device type, dates, problems, etc.

The Medical Devices Bureau can also act as a regulatory branch and has several options ranging from the negotiation with a manufacturer to find a solution, revoking licences, stopping sale of products and banning importation. In a non-regulatory capacity the Medical Devices Bureau can also request a manufacturer's advisory to users, release a Health Canada Advisory to users or issue a Health Canada press release in extreme cases.

Interested individuals who would like to be proactive within their own organizations can subscribe to Health Canada's email update list serve by visiting the web site:

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_professionals_e.html#2002

(For further information Dr. Neufeld's presentation slides are provided in the appendix).

Patient Safety Issues Facing Us Today

Within the context of the day much discussion took place among the assembled members. While the driving theme was, of course, patient safety, there emerged many sub-themes. These sub-themes and comments, ideas and viewpoints are provided below to give deeper context to the patient safety issues discussed.

Timeliness of Communication

- Health Canada advisories being released in a timely fashion so as to facilitate information sharing with health care organizations and to acknowledge families and communities concerns.
- The need for "at the time of need" communication between Health Canada and expert members of CAPHCs membership to expedite decisions that need to be made to support the advisory process.
- Organizations and individuals alike need to make use of technology to improve the speed of communication, the example of list serves was given as a demonstration technology helping to convey information in a fast and efficient way.

The Role of Advocacy

- As individual CAPHC members and for the official mandate of CAPHC the role of advocacy could be a powerful change agent in creating improved systems for patient safety.
- In order to affect change with manufacturer produced equipment advocacy must play a role in changing the public perception. There could be a role to educate the public and then advocate from this perspective.

Removal of Name/Blame/Shame Cultures Within Our Organizations

- Creating practices, procedures and policies that shift our working cultures away from naming who made an error, blaming individuals and shaming them publicly. Building organizational systems that support the review of system failures and not individual errors will help toward improving patient safety.

Consultation and Collaboration

- Improved consultation and collaboration between all stakeholders is necessary. Identified stakeholders include; CAPHC membership, Health Canada, manufacturers and patients and their families.
- Improved consultation and collaboration could take the form of a CAPHC advisory panel for linkages with Health Canada and an improved consultation process with Health Canada advisories.

Resource Issues

- All healthcare organizations are working with varying degrees of limited resources. Any ideas to improve communication, collaboration, information sharing, etc between stakeholders must balance the need for optimal management of resources and patient safety.

July 2002 Notice to Hospitals- Recommended Revisions and Discussion

The original July 2002 Health Canada directive follows.

Health Canada
Health Products and Food Branch
Direction générale des produits de santé et des aliments

The Marketed Health Products Directorate (MHPD), Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD) posts safety alerts, public health advisories, press releases and other notices from industry as a service to health professionals, consumers, and other interested parties. Although MHPD, TPD and BGTD approve therapeutic products, MHPD, TPD and BGTD do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

NOTICE TO HOSPITALS
from the Marketed Health Products Directorate,
Therapeutic Products Directorate and the Health Products and Foods Branch Inspectorate

July 30, 2002

To: Hospital Chief of Medical Staff

Please distribute to the relevant Departments of Anaesthesia, Intensive Care, Emergency, Nursing, Pediatrics, Surgery and other involved professional staff and **post this NOTICE** in your institution.

**Risk of Strangulation of Infants by IV Tubing
and Monitor Leads**

Health Canada is concerned about reports of suffocation and death in young children caused by entanglement in IV tubing when children are treated in hospital. Young children are at risk of strangulation from any type of cord, whether these are consumer products such as blind cords, or medical devices such as electronic leads or IV tubing. Leaving a child unattended in any environment where entanglement with a cord, tube, or lead is possible may have disastrous consequences.

Health Canada recommends the following:

1. All hospitalized children who could possibly become entangled in a lead or tubing should be continuously observed by an adult or placed on a monitor.
 2. Consider treating hospitalized children with oral therapy, or a heparin-locked needle if possible.
 3. Coil excess tubing when the child is unattended to prevent the infant/child from becoming entangled.
 4. Inform hospital staff, parents, and other care-givers that young children are at risk of entanglement and strangulation by IV tubing, electronic leads, or cords of any sort.
-

After much discussion a consensus was reached and the following changes in the directive were agreed upon:

**Health Canada
Health Products and Food Branch**

NOTICE TO HOSPITALS

December 10, 2003

To: Hospital Chiefs of Medical and Nursing Staff
Please distribute to the relevant Departments of Paediatrics, Anaesthesia, Intensive Care, Emergency, Nursing, Surgery and other involved professional staff and **post this NOTICE** in your institution.

UPDATE: Risk of Strangulation of Infants by IV Tubing and Monitor Leads

This is an update to the information in the Health Canada Notice to Hospitals dated July 30, 2002. The recommendations in the Notice were discussed by representatives of Health Canada, the Canadian Association of Paediatric Health Centres (CAPHC), and family advocacy groups at a special meeting held June 14, 2003, in Calgary, AB.

The discussion focussed on CAPHC members' concerns that it would not be feasible for healthcare institutions to implement some of the recommendations in the Notice. A paper published shortly before the meeting¹ described two cases in Canada of strangulation involving IV tubing, and proposed preventive measures. Discussions at the meeting, and further consultation between Health Canada and CAPHC have resulted in the following revised recommendations which have been endorsed by both parties.

Health Canada and CAPHC recommend the following:

The hospital environment requires high vigilance by staff in order to avoid adverse incidents that may stem from the use of products and equipment used in diagnosis, prevention, and treatment.

Acute care facilities (tertiary and quaternary), regional and community health care centres, rehabilitation centres, and community and home care organizations should establish policies and procedures that include a risk assessment for each patient, made in consultation with the patient's family. These policies should consider such measures as:

1. Using continuous IV administration only when necessary. For intermittent IV infusion, saline or heparin-locked IV sites should be considered.
2. Providing an appropriate level of supervision for children who have entangled themselves in tubing, including oxygen tubing, or leads, or are considered to be at an increased risk of doing so. Factors to be considered might include:
 - the child's age and cognitive level
 - the child's mobility and state of agitation

- the length and number of tubes and leads attached to the patient

3. Using equipment accessories that restrain or stabilize flexible lines to reduce the potential for them to become wrapped around the child's neck or limbs.

Health Canada evaluates therapeutic products for quality, safety, and efficacy. Their actual use in therapeutic settings is a responsibility of healthcare providers. Health Canada and CAPHC ask that you share these recommendations with your staff or membership and encourage their implementation in the interest of patient safety.

If you have any concerns, problems or complaints pertaining to medical devices, you should report them to Health Canada at the address below, or through a toll-free line at 1-800-267-9675.

Health Products and Food Branch Inspectorate
Health Canada
Tower "A", Holland Cross
11 Holland Ave.
Address Locator: 3002C
Ottawa, Ontario K1A 0K9

References

1. Garros D, King WJ, Brady-Fryer B, Klassen TP. Strangulation With Intravenous Tubing: A Previously Undescribed Adverse Advent in Children, *Pediatrics* 111:e732-e734, 2003.
<http://pediatrics.aappublications.org/cgi/content/full/111/6/e732>
-

Within the discussion regarding the Health Canada advisory an important contextual issue was brought to light.

Consideration given to families involved was noted as a priority throughout the process. In not losing sight of the parent's needs several ideas and strategies were suggested.

- Health Canada could inform the families involved about the Patient Safety Workshop objectives and outcomes.
- Advise them of changes and preview material prior to its public distribution.
- Designate a contact person at Health Canada for the families to communicate with, should they desire.
- Provide a full and comprehensive explanation of why the first Health Canada Directive wasn't working for hospitals nation wide.

All members at the table agreed that the sole purpose of the Patient Safety Workshop was to prevent such a tragedy from happening again and that families who are involved should be treated with the utmost care and regard with reference to interventions and initiatives after the fact.

Future Collaboration- Communication Strategies

Throughout the course of the Patient Safety Workshop it was noted by all stakeholder groups, CAPHC, Health Canada and family representation, that future collaboration is imperative.

Collaborative efforts could include:

- The formation of a multi-stakeholder working group to assess ideas generated from the Patient Safety Workshop and to provide guidance and direction on initiatives to move forward with.
- Continued communication between Health Canada and CAPHC surrounding patient safety issues in reference to health care organizations and the implementation of advisories issued by Health Canada.
- An acknowledgement of the various stakeholder groups and what each can bring to the discussion of patient safety.

Multi Stakeholder Working Group

The following individuals, representing a variety of areas, have agreed to sit on the Multi Stakeholder Working Group.

Elaine Orrbine, Chief Executive Officer
Canadian Association of Paediatric Health Centres (CAPHC)
National Office – Ottawa Ontario

Martine Dube, Nurse Manager
Ste. Justine Hospital

Dr. Fred Lapner, Section Head
Medical Devices Bureau, Health Canada

Morag McKay, Director, Plan-It Safe
Children's Hospital of Eastern Ontario, Ottawa

Dr. Supriya Sharma, Director of Marketed Health Products Directorate
Health Canada

Dennise Albrecht, Director of External Affairs
Children's Hospital of Eastern Ontario

Donna Carr, CHS Director for Neonatology
Hospital for Sick Children, Toronto

Kim Shearer, Manager Special Product Quality Practices and Nursing
British Columbia Women's and Children's Hospital

Peggy Sangster, Manager Quality Management of Paediatric Sites, Montreal

Dr. Terry Klassen, Chair, University of Alberta, Faculty of Medicine & Dentistry's
Department of Pediatrics
and
Regional Clinical Program Director, Capital Health's Stollery Children's Hospital and
Regional Child Health Program
Edmonton, Alberta

Ms. Michele Lahey (Chair, Multi-Stakeholder Working Group)
Chief Operating Officer, Capital Health's University of Alberta Hospital and
Stollery Children's Hospital
Edmonton, Alberta

Corrine Frick, Director of In-Patient Children's Programs
Alberta Children's Hospital
Calgary, Alberta

Polly Stevens, Director, Quality and Risk Management
The Hospital For Sick Children
Toronto, Ontario

Dr. Anne Matlow, Director, Infection & Control Programme
The Hospital For Sick Children
Toronto, Ontario

Ms. Barb Brafy-Fryer Patient Care Director
Child Health, Stollery Children's Hospital and
Royal Alexandra Hospital, Edmonton

Ideas for Review

From the issues discussed by all stakeholders many ideas for further development were noted.

Idea suggested	Responsible for evaluating
<ul style="list-style-type: none"> Creation of an electronic list serve for CAPHC membership to share patient safety issues, concerns, ideas, resources and best practices. 	<ul style="list-style-type: none"> Multi stakeholder working group
<ul style="list-style-type: none"> Formation of Interdisciplinary Pediatric Advisory Team to be accessible to Health Canada on an “as needed” basis for timely consultation on Health Canada Advisory issues. 	<ul style="list-style-type: none"> Multi stakeholder working group
<ul style="list-style-type: none"> Creation of a new Health Canada directive to hospitals to replace the July, 2003 directive. New directive to have followed a consultative approach and to take into account issues raised by stakeholder groups. 	<ul style="list-style-type: none"> CAPHC and Health Canada
<ul style="list-style-type: none"> Develop an anonymous database of near miss events, across CAPHC membership, to accurately collect information with the name/blame/shame issue. 	<ul style="list-style-type: none"> Multi stakeholder working group
<ul style="list-style-type: none"> Develop an electronic registry of off-label and adapted devices for CAPHC membership to share information regarding paediatric medical equipment. 	<ul style="list-style-type: none"> Multi stakeholder working group

Summary

The Patient Safety Workshop was designed to address the risk of infant strangulation and other emerging patient safety issues within a consultative and collaborative forum. The primary goals of the workshop were:

- To acknowledge and link our common goals and priorities for patient safety.
- To develop a framework for continued partnerships and communication around patient safety issues
- To respond to Health Canada's Notice to Hospitals dated July 30th, 2002 regarding the Risk of Strangulation of Infants by IV Tubing and Monitor Leads.

The overall strength of this workshop was highlighted in the demonstrated capacity to bring together partners from many disciplines and sectors to address the broader issues associated with ensuring optimal patient safety for all children at risk within health care settings across the country.

Common goals and priorities were discussed and acknowledged, ideas for continued communication frameworks were generated and a consultative revision of Health Canada's Notice to Hospitals, dated July 30th, 2002, was drafted.

The Patient Safety Workshop achieved more than its original goals. It also began a larger framework from which to build on concerning patient safety in paediatric health centres. These additional outcomes include:

- The formation of a Multi Stakeholder Working Group designed with the intention of addressing issues and possible solutions in paediatric patient safety
- The formation of a more tangible link between Health Canada and CAPHC to assist in the consultation process needed for future patient safety issues.

It was acknowledged that with the primary goals of the workshop and the secondary additional outcomes achieved future efforts to improve patient safety were greatly increased by the June, 14th Patient Safety Workshop.

Patient Safety Workshop Appendix

**Health Canada /Canadian Association of Paediatric Health Centres
Patient Safety Workshop**

June 14, 2003, 8:30 AM– 4:30 PM

Hyatt Regency Hotel

Calgary Alberta

Agenda

8:00 – 8:30	Registration and Continental Breakfast	
8:30 – 8:45	Welcome & Introductions Opening Remarks	Elaine Orrbine
8:45 – 9:00	Overview and Goals of Workshop	Dennise Albrecht (Workshop Facilitator)
9:00 – 9:45	Key Note Address	Dr. Jim King
9:45 - 10:00	Break	
10:00 – 10:45	Case Study	Ms. Barb Brady-Fryer
10:45 – 11:00	Medical Devices Regulations	Dr. Fred Lapner
11:00 – 11:15	Post Market Surveillance	Dr. Philip Neufeld
11:15 – 12:00	Panel and Open Discussion	
12:00 – 12:45	Lunch (informal discussion)	
12:45 – 1:00	Overview of Afternoon Workshop	Dennise Albrecht
1:00 – 3:00	Interactive Round Table discussions & Recommendations	
	i. Addressing the July 2002 – “Notice to Hospitals”	
	ii. Establishing formal consultation/communication linkages between Health Canada and the Child and Youth Health care Community	
	iii. Emerging Patient Safety Issues	
3:00 – 3:15	Break	
3:15 – 4:15	i. Endorsement of Recommended Revisions Regarding: ▪ “Notice to Hospitals” ▪ Establishing National Linkages	
	ii. Time lines and process re workshop proceedings and final recommendations to Health Canada	
	iv. Next Steps	
4:15 – 4:30	Closing Remarks & Adjournment	

Patient Safety Workshop Participant List

Name	Title	Institute	Phone	Email
Abraham, Marilyn	Program Development Manager for NICU and Regional Paediatrics	St. Joseph's	(416) 530-6000	ABRAHM@stjoe.on.ca
Albrecht, Denise	Facilitator	CHEO	(613) 737-2393	albrecht@cheo.on.ca
Brady-Fryer, Barb	Patient Care Director, Child Health	Capital Health Stollery Children's and Royal Alexandria, Edmonton	780-491-5537	bbrady-f@cha.ab.ca
Brodie, Dennis	Senior Policy Advisor	Therapeutic Products Directorate, Health Canada		Dennis_Brodie@hc-sc.gc.ca
Carr, Donna	CHS Director for Neonatology	Toronto Sick Kids	(416) 813-8956	donna.carr@sickkids.ca
Cooke, Carole		CHEO	(613) 737-2393 x2742	cooke@cheo.on.ca
Crawford, Pat	Nurse Manager	Orillia Memorial		pd Crawford@osmh.on.ca
Dube, Martine	Nurse Manager	Ste Justine	(514) 345-4748	martine_dube@ssss.gouv.qc.ca
Fleming, Joy	Assistant, CAPHC	CAPHC	(613) 738-4164	jffleming@caphc.org
Follett, Joan	Surgical Division Manager	Janeway, Newfoundland		hcc.foljoa@hccsj.nf.ca
Frampton, Bill	Administrator	Orillia Memorial	(705) 325-2201	bdf Frampton@osmh.on.ca
Frick, Corine		Alberta Childrens		corine.frick@calgaryhealthregion.ca
Ganton, Joanne	Calgary	Alberta Childrens		jganton@telusplanet.net
Garros, Dr. Daniel	PICU attending physician	Stollery Childrens		dgarros@cha.ab.ca
Gavin, Frank	National Family Advisory Group		(416) 484-6486	frankgavin@rogers.com
Harvie, Margot	Calgary	Alberta Childrens		margot.harvie@calgaryhealthregion.ca
Janes-Kelley, Selikke	Senior Operating Officer	Health Sciences Centre, Edmonton		sjaneske@cha.ab.ca
King, Dr. Jim	Keynote Speaker	CHEO	(613) 737-2393	king@cheo.on.ca
Lapner, Dr. Fred	Section Head	Medical Devices Bureau, Health Canada		Fred_Lapner@hc-sc.gc.ca
Mainland, Sheena		Alberta Childrens		sheena.mainland@calgaryhealthregion.ca
Mardlin-Smith, Ferne		IWK	(902) 470-7254	ferne.mardlinsmith@iwk.nshealth.ca
Mcintyre, Mary	Nurse Manager	London		mary.mcintyre@lhsc.on.ca
McKay, Morag	Director	CHEO	(613) 737-7300 x 3983	mmackay@cheo.on.ca
Neufeld, Dr. Philip	Manager, Device Surveillance Division	Medical Devices Bureau, Health Canada		Philip_Neufeld@hc-sc.gc.ca
O'Brien James, Mara	Transcriber	CHEO	(613) 737-2393	mobrienjames@cheo.on.ca
Orrbine, Elaine	CEO, CAPHC	CAPHC	(613) 738-4164	eorrbine@caphc.org
Pardy, Marilyn	Director, Child Health	Janeway, Newfoundland	(709) 777-4423	Marilyn.Pardy@hccsj.nf.ca
Richards, Nancy	Manager, Operations and Coordination	Director General's Office, Health Canada		Nancy_Richards@hc-sc.gc.ca
Rosen, Ellen		London		ellen.rosen@lhsc.on.ca
Sharma, Dr. Supriya		Marketed Health Products Directorate, Health Canada		Supriya_Sharma@hc-sc.gc.ca Ana_Mayorga@hc-sc.gc.ca
Shearer, Kim		Children's & Womens Health Centre		kshearer@cw.bc.ca
Van Stolk, Dori	Project Consultant, Nursing	Children's & Womens Health Centre		dvanstolk@cw.bc.ca

Strangulation With Intravenous Tubing: A Previously Undescribed Adverse Advent in Children

Daniel Garros, MD*‡; W. James King, MD§||; Barbara Brady-Fryer, RN, MN‡¶; and Terry P. Klassen, MD*‡

ABSTRACT. Nonintentional strangulation in children is a widely recognized risk as a result of the vulnerability of their airway to occlusion by relatively low pressures. We describe 2 cases of strangulation by intravenous (IV) tubing in infants, 1 of which was fatal. This is the first documentation in the health science literature of this as a potential adverse consequence of IV therapy in young children. It is important that hospitals that care for such children recognize this potential risk and implement the appropriate strategies to minimize or eliminate it. Preventive interventions may include ongoing assessment of the need for continuous rather than intermittent IV infusions (saline or heparin locked IV sites), individualized level of supervision according to the child's age and behavior, and engineering modifications to the IV equipment. *Pediatrics* 2003;111:e732–e734. URL: <http://www.pediatrics.org/cgi/content/full/111/6/e732>; wounds and injuries, asphyxia, suffocation, accident, infants, safety management, beds, airway obstruction, prevention, hospital practice.

ABBREVIATIONS. IV, intravenous; PICU, pediatric intensive care unit.

Nonintentional self-strangulation of children with loose wires, cords, or other potential ligatures in or adjacent to sleeping areas is well-described.^{1,2} A recent study from the US Consumer Product Safety Commission analyzed 2178 fatalities that occurred between 1980 and 1997, describing several patterns of unintentional infant suffocation. "Entanglement" leading to strangulation was responsible for 14.3% of the fatalities. Plastic bags, bedding (nonplastic), blind/drapery cords, pacifier cords, and other types of cords were the most common sources.³

Intravenous (IV) therapy is a common treatment modality for children who are admitted to a hospital; hence, if there is a serious risk of strangulation associated with its use, then it is critical that health care providers be aware of it. With the help of a qualified health librarian, we searched the health literature

and could find no previous description of this risk. We present 2 cases of mechanical asphyxia caused by IV tubing, 1 of which was fatal.

CASE REPORTS

The first case involved an 11-month-old boy who had a history of prematurity and mild respiratory distress syndrome after being born at 28 weeks gestation and who remained in the neonatal intensive care unit for ~3 months. After being home for 8 months, the child was admitted to the hospital with a diagnosis of pneumonia and dehydration. Although his motor development was somewhat delayed as a result of his prematurity, during his hospitalization the child could roll, sit, and pull himself to stand in the crib. He was treated with oxygen therapy, IV fluids, and antibiotics. During the 24 hours before this fatal strangulation, the nurses and mother had noted the child to become entangled in IV tubing 3 or 4 times around either the abdomen or the legs. On the day before his planned discharge, he was receiving IV antibiotics but no longer required oxygen therapy. The last nursing check was done at 1630 hours, at which time the child was stable. The parents went home at that time. However, at 1715 hours, the nursing staff found the child lying in his crib apneic and pulseless with the IV tubing wrapped 3 times around the neck. A cardiac arrest code was called, and after 22 minutes of resuscitation, including intubation and 3 doses of IV epinephrine, bicarbonate, and atropine, he regained a hemodynamically stable cardiac rhythm. He was then transferred to the regional pediatric intensive care unit (PICU). On physical examination, there were erythematous marks around the child's upper neck consistent with strangulation marks by IV tubing, and the child had seizures on arrival. Both pupils became fixed and dilated. Because there was no chance for meaningful recovery, the family agreed to withdraw therapy 48 hours after admission to the PICU. The autopsy was consistent with death resulting from asphyxial damage from the IV strangulation. The IV pump (IMED, Alaris 960 A; Alaris Medical Systems, San Diego, CA) was examined by the hospital biomedical engineering department and was found to be operating as per the manufacturer's specifications. The length of the IV tubing, which extended beyond the IV pump to the patient, was 165 cm.

The second case involved an 8.5-month old boy who was transferred from a peripheral hospital to the regional children's hospital with an invasive group A streptococcal cellulitis, secondary to chickenpox. Meningitis, pneumonia, bilateral otitis media, and anemia complicated his hospitalization. During the admission, he experienced a right-sided focal seizure, and neuroimaging revealed left occipital lobe abscess and a left superior parietal cerebritis. Cerebrospinal fluid cultures were positive for enterococcus. One month after admission, he was still receiving IV antibiotics through a percutaneously inserted central catheter for the enterococcal abscess and meningitis. One evening, at 1800 hours, the nursing staff performed a routine assessment and noted that his percutaneously inserted central catheter line was infusing well. At 1825 hours, he was observed by nursing staff to be sitting in his crib awake, then at 1835 hours was found sitting forward with his head on his lap and the IV tubing wrapped tightly 2 times around his neck. The tubing was 304 cm in total length from the bag, filling chamber, IV pump segment, and the extension to the patient. He was noted to be pulseless and apneic and hence cardiopulmonary resuscitation was initiated. He received full cardiorespiratory resuscitation with intubation, although he was noted to gasp after initial mouth-to-mouth respiration. During resuscitation, he had 2 generalized clonic seizures. The child was

From the *Department of Pediatrics, University of Alberta, Edmonton, Alberta, Canada; †Stollery Children's Hospital, Edmonton, Alberta, Canada; ‡Department of Pediatrics, University of Ottawa, Ontario, Canada; §Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canada; and ¶Faculty of Nursing, University of Alberta, Edmonton, Alberta, Canada.

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Reprint requests to (D.G.) Pediatric Intensive Care Unit, Stollery Children's Hospital, 3A3.03 WMC, 8440-112 St, Edmonton, Alberta, Canada T6G 2R7. E-mail: dgarros@cha.ab.ca

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Fig 1. IV tubing enclosed in a plastic sleeve to prevent entanglement.



subsequently transferred to the PICU, and he eventually made an uneventful recovery. Neuropsychological assessment 2 weeks after the event, at 10 months of age, revealed a mild delay in cognitive (7 months) and motor function (8 months) but advanced social skills (12 months).

DISCUSSION

We believe that these are the first 2 cases of IV tubing strangulation described in the health literature. Our biomedical engineers accessed a database created by the Emergency Care Research Institute, which briefly describes 2 cases of fatal strangulation by IV tubing in the United States occurring in 1984 and the other in 1997. The actual risk of IV tubing strangulation in children is not known. As in other areas of medical misadventure, there may be an underreporting of this type of event.

The risk associated with cords placed close to children is well-described in the literature.^{2,3} We found 1 case of nonfatal strangulation by the wires from an apnea monitor in a child.⁴ The force necessary to asphyxiate a child seems to be relatively small⁵; therefore, they are particularly vulnerable to this airway compromise.

As in most areas of injury, prevention remains the best strategy. As any injury prevention initiative, passive primary interventions need to be implemented. First, it is important to examine critically the need for IV therapy in any child who is admitted to a hospital. If continuous fluid administration is not required but IV access is still needed, then the use of locking devices for peripheral and central lines is indicated. In our estimation, risk is related to the child's cognitive level, age, mobility, and the length of the IV tubing. The number of fatalities caused by entanglement was significantly higher in the group of children older than 7 months in the study by Drago and Danenberg.³ In addition, the overall number of tubings and lines (eg, oxygen tubing, pulse oximetry, electrocardiographic leads, IV lines) required for care may increase the risk of strangulation; however, we do not have any data to support

this. It is not infrequent to see IV lines and other cables tangled when patients are very mobile, perhaps increasing the risk of pulling and tightening them around their limbs. Nonetheless, children who need more than 1 IV line and several other types of cords (saturation cable, electrocardiogram monitor leads, etc) are usually sicker, hence less mobile and under more constant supervision.

As another primary active prevention strategy, it is necessary to focus on reducing the potential of flexible lines and tubings to "wrap" and thus encircle limbs or the neck. A Canadian entrepreneur has developed a rigid, clear plastic sleeve that may be placed on the IV and any other tubing/wire close to the child. This device prevents the tubing from wrapping, while maintaining the function of the device and mobility of the child (see Fig 1).

As secondary active prevention initiative, the level of supervision necessary for any child needs to be scrutinized. For example, all children who are between 3 months and 3 years of age and admitted to the Stollery Children's Hospital and require IV therapy are evaluated regarding risk factors for entanglement. The bedside nurses, following a specific "policy and procedure" guideline, evaluate the potential risk on a shift-to-shift basis and take appropriate nursing actions on the basis of the risk assessment. Interventions for children who are deemed to be at risk include increasing the level of staffing or moving the child to a location where he or she can be observed more frequently.

To our knowledge, these are the first cases in the medical literature to describe strangulation by IV tubing; thus, it is important to recognize this as a potential adverse event in children who receive IV therapy. Carefully selecting patients for IV therapy, evaluating the appropriate level of supervision according to the child's age and behavior, and working with the industry to design safer systems should help to ensure that hospitals become safer places for children.

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Objectives

Pediatric Injury - Bridging the Gap

- ▼ Overview of injury, medical error and patient safety
- ▼ Injury control concepts

Definitions

▼ Error*

- failure of planned action to be completed as intended (error of execution) or use of wrong plan to achieve an aim (error of planning)

▼ Safety*

- freedom from (accidental) injury.

▼ Injury

- acute exposure to or absence of an external agent(s) regardless of intent
- external agent
 - Energy source: Mechanical/Thermal/Chemical/Kinetic/Radiant
 - Absence of Heat or Oxygen

*Institute of Medicine, 2000

Historical

- ▼ Live with the fears of our grandparents
- ▼ Redefine the unacceptable
- ▼ Injury
- ▼ Patient Safety

Patient Safety

To Err is Human: Building a Safer Health System

- ▼ Dec '99 IOM report on medical errors
 - 44,000 to 98,000 people die / year
 - occur in hospital
 - medication errors account for 20%
- ▼ Cost of \$17 - \$29 billion to society
 - \$8.8 billion in direct health care costs

Patient Safety

Top Ten Causes of Death, 1998

1	Heart Disease	724,269
2	Cancer	538,947
3	Cerebrovascular Dis	158,060
4	Pulmonary Disease	114,381
5	Medical Errors	98,000 (est)
6	Pneumonia/Influenza	94,828
7	Diabetes	64,574

Patient Safety

Average Fatal Accident Frequency Rates

deaths per million hours of exposure

Being pregnant	1
Working at home	8
Being in traffic	50
Working in construction	67
Flying commercially	100
Being a hospitalized patient	2000
Being anesthetized	2000
Parachute jumping	20000
Having elective AAA surgery	200000

Adapted from Zelders

Patient Safety

To Err is Human: Building a Safer Health System

▼ ?Are the numbers right?

- Errors are often addressed privately and quietly.

▼ To Err is Human

- based on data from 2 centres: ?overestimate
- many patients were end of life
- no outpatient data ? Adverse event rates higher

Patient Safety

To Err is Human: Building a Safer Health System

▼ Redefine the unacceptable

▼ 4 points

- Injury problem is serious
- Cause faulty systems
- We need to redesign these systems
- Safety needs to be a priority

Patient Safety

IOM

▼ Agenda to Redesign 21st Century Health Care System

- Commit to six aims for improvement
- Adopt ten principles to guide redesign of care
- Focus initially on priority health conditions
- Implement effective organizational supports
- Create environment that fosters improvement

Patient Safety

IOM

▼ Agenda to Redesign 21st Century Health Care System

- Commit to six aims for improvement.

Health care should be:

- Safe
- Effective
- Patient-centered
- Timely
- Efficient
- Equitable

} Core Dimensions of the
Quality of Individual
Medical Care

Patient Safety

Matrix for Measures of Quality

Consumer Perspectives on Health Care Needs	Components of Health Care Quality			
	Safety	Effectiveness	Patient-Centeredness	Timeliness
Staying Healthy				
Getting Better				
Living with Illness or Disability				
Coping with End of Life				

Patient Safety

- ▼ Medical Error vs System Failure
- ▼ Active harm vs failure to do right.
- ▼ Using errors limits scope
- ▼ Shift focus: Medical Injuries
- ▼ Most injuries result in little harm
- ▼ The Heinrich Ratio

Injury Control Concepts

3 Basic Injury Facts

- ▼ Injuries are a Disease
- ▼ Injuries are not accidental
 - predictable; risk factors are identifiable
 - preventable
- ▼ Injury prevention is an investment

Injury Control Concepts

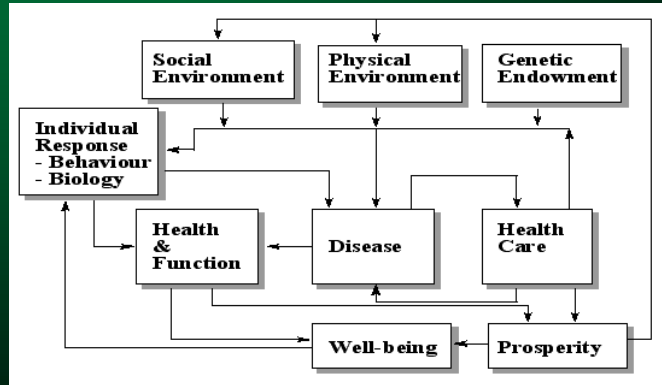
- ▼ Engineer: William Haddon
 - Lack of distinction between Injury and Disease
 - Evaluation of individual level risk factors

▼ Haddon Matrix

Phase	Agent	Host	Environment	
			Physical	Social
Pre-event				
Event				
Post-event				

Injury Control Concepts

Evaluation of population level risk factors

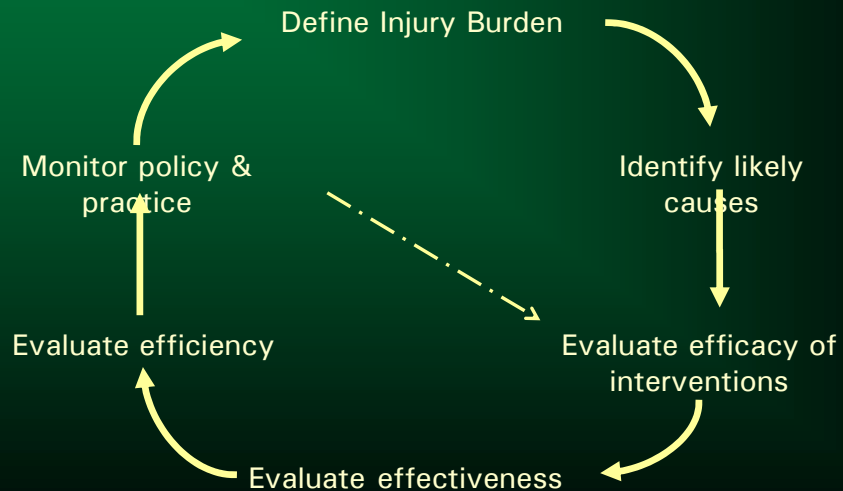


Source: Evans RG, Stoddart GL. Producing health, consuming health care, *Social Science and Medicine*, 31;12:1347-1363, 1990.

Injury Control Concepts

Iterative Loop

Modified from Tugwell P et al, 1985



Patient Safety

Children Unique Risk

- ▼ Medical injury rate is similar to adults
- ▼ Large, ten-fold errors in dosing
- ▼ Off-label drug/device usage
- ▼ Limited reserve to withstand an injury
- ▼ Limited ability to communicate

Patient Safety

Implications

- ▼ Pediatric Health Professionals are uniquely situated to address the risk
- ▼ Leadership
- ▼ Demonstrate success

Key Points

- ▼ Shift focus: Medical Errors to Injuries
- ▼ Safety can best be improved by a systems approach
 - Injury control context and Iterative process
- ▼ Children Unique Risk
- ▼ Leadership from individuals, organizations, and social policy

Redefine the unacceptable

Health Canada/CAPHC Patient Safety Workshop

Case Study Strangulation with intravenous tubing: A sentinel event

Barbara Brady-Fryer RN, PhD (c)
June 14, 2003



Case Study Outline

- Describe the event
- Summarize organization initiatives:
 - take immediate action
 - identify underlying causes
 - develop effective interventions
 - address future prevention
- Lessons learned



Background

- 11 month old infant
- born 28 weeks gestation, 15 weeks in NICU
- home for 8 months
- presented with cough/emesis, nasal congestion, fever, decreased O2 saturation
- query RUL pneumonia, dehydration
- admitted general pediatrics ward
- bronchodilators, O2, antibiotics, IV fluids (hand)



Background

- motor development appropriate for post-conceptual age - could roll, sit and pull to stand in a crib
- cried vigorously when upset
- parents generally in attendance, except to care for older sibling (also ill)
- entanglement in IV tubing noted by mother and staff during hospitalization – legs and abdomen



Incident

- improved after 24 h, O2 d/c, IV - KVO for antibiotics, for discharge in AM
- checked at 1645 h, stable, parents home
- 1720 h check – to receive IV medication
- found with tubing wrapped 3 times around neck, apneic, pulseless, code called
- resuscitated X 22 min to obtain stable HR
- transferred to regional PICU on life support



Immediate Response

- collect/document basic information - critical incident report
- support family and staff
- respond to media requests for information
- internal/external stakeholder communication
- review case at M & M Rounds
- establish inter-disciplined Task Force
- respond to Medical Examiner



Identification of underlying causes

- Contextual factors around the event ?
- Equipment failure ?
- Failure to follow standard practices/ procedures ?
- Barriers to or lack of appropriate communication ?
- Evidence of other events of this nature ?



Development of effective interventions

- Initial actions
 - systematic analysis of event particulars
 - voluntary/mandatory reports – HC, ECRI, FDA
 - benchmark standard practices
 - search literature for reports of similar incidents
 - review device databases
 - “entanglement incident” data collection



Development of effective interventions

Intermediate actions

- **Develop and trial strategies to reduce/manage risk:**
 - **Reduce IV use – re-hydration protocols, IV locking devices → policy, SR IV lock flushes**
 - **Use of restraints for patients with IVs**
 - **Change length of tubing – coils, clamps**
 - **Pump technology – PCA, portable pumps**
 - **Prevent IV tubing from “wrapping” – sleeves**
 - **Measures to individualize care of patients with IVs → policy**



Prevention for the future

- Respond to recommendations from Fatality Inquiry
- Publish – *Pediatrics*, June 6 2003
- Health Canada/CAPHC Patient Safety Workshop



Lessons Learned

- We need to open our eyes to the environmental risks to patient safety
- There is a tradition of non-reporting of incidents
- Working with families is extremely challenging and complex
- Staff require an enormous amount of support
- Knowledgeable, consistent leadership is critical to ensure “best” outcomes



Lessons Learned

- Infrastructure exists to share critical information with stakeholders but it can (should be) be improved to enhance communication, share evidence, prevent “re-invention” of the wheel, promote consensus, and enhance patient safety

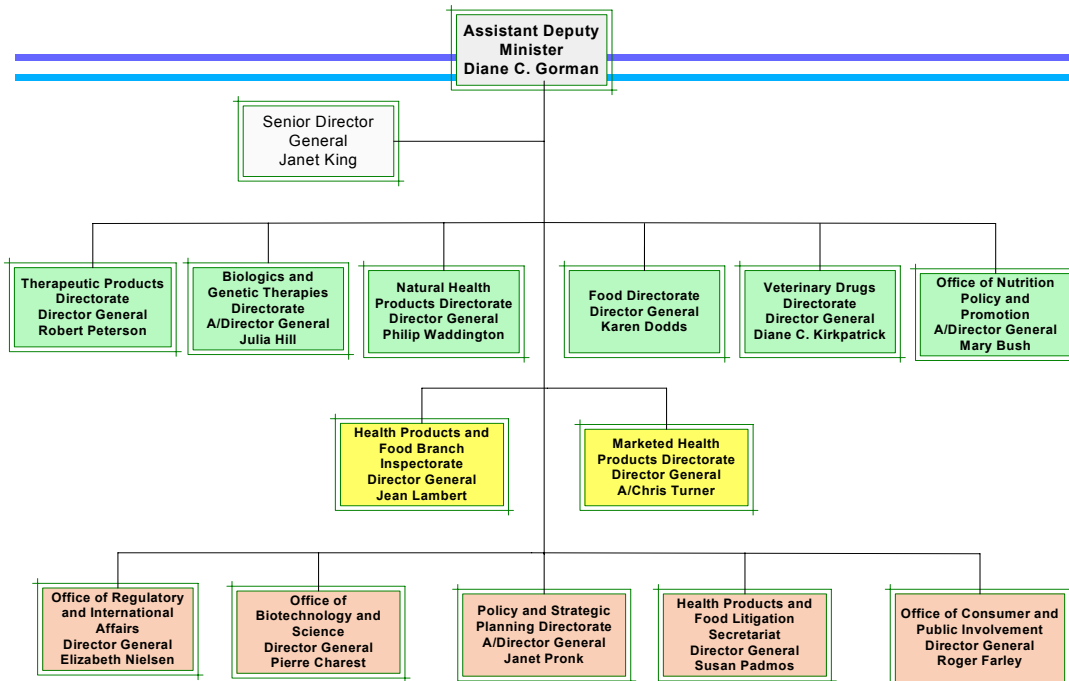


Medical Devices Regulations Pre-Market Considerations CAPHC Workshop- 14 June 2003

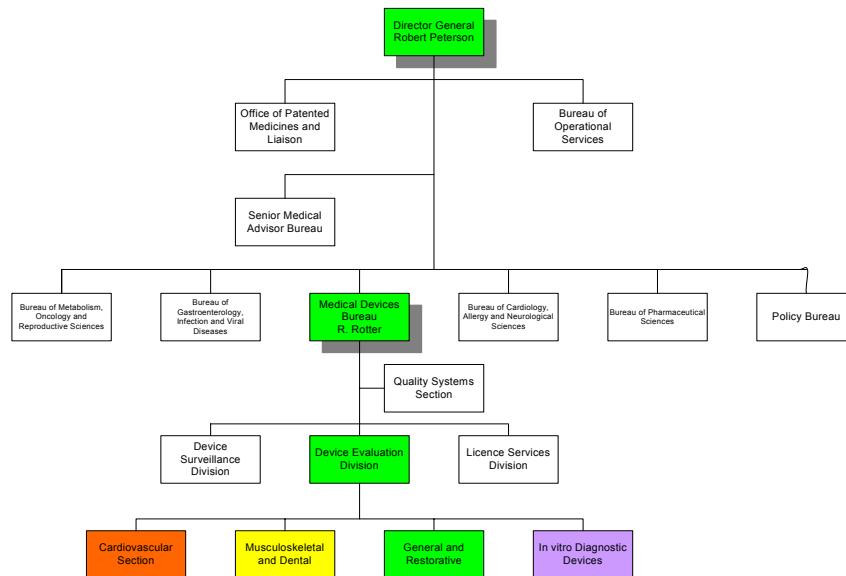
Fred Lapner, M.D.
General & Restorative Devices Section
Medical Devices Bureau

Health Products and Food Branch
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HEALTH PRODUCTS AND FOOD BRANCH




Therapeutic Products Directorate



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Medical Device-Definition

 Any article, instrument, apparatus or contrivance...including any component/accessory

- Diagnosis, treatment, prevention...disease, disorder abnormal physical state or its symptoms
- Restoring, correcting, or modifying a body structure
- Diagnosis of pregnancy
- Care during pregnancy and birth

Not a Drug



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Medical Devices Regulations

1998- New Regulations

- Concept of Risk Classes (Classification Rules)
- Risk reduction
- Standards requirements
- Problem Reporting
- Quality Systems



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Part 1: General Requirements

Safety and Effectiveness Requirements (sections 8 – 20)

Labelling Requirements (sections 21 - 23) Requirement for GMP's

Application for a Medical Device Licence (Section 32)



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Device Licencing

- 🔔 Section 26: manufacturer of Class II, III and IV devices must hold a licence before selling a medical device in Canada.
- 🔔 Section 32: applications for Class III and IV devices require documentation to substantiate the safety and effectiveness of the device.



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The Premarket Review Document

- 🔔 Required for Class III and IV medical devices
 - and Class II's if new technology/concerns.
- 🔔 contains the objective evidence required to determine if the new/amended device licence application meets the safety and effectiveness requirements of the Regulations.
- 🔔 Guidance document(s) describe the format and content of this file.



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Premarket Review Document-Class III

- Executive Summary
- Background information
- Device specific information
- Summary of S&E studies
 - ⇒ Declaration of Conformity to Standards
 - ⇒ Labelling & Operator's Manuals



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Quality Systems Requirements

 ISO 9001:2000 and ISO 13485:1996

-  Development
-  Design
-  Supply
-  Production
-  Installation
-  Service



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Guidance/References

- ⇒ Recognized Standard
 - ⇒ Device Specific (Vertical)
 - ⇒ Horizontal (e.g. Biocompatibility/Sterilization)
 - ⇒ International /National Standard

- ⇒ MDB Guidance Document
- ⇒ FDA Guidance Document (for reference)

- ⇒ Literature Studies



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QS regulatory requirements



**Valid ISO 13485/8-1996 QS system certificate
from a CMDCAS recognized registrar**

All new/amendment device licence applications

1 January 2003

All current Class II, III & IV licences at renewal

November 2003



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POST-MARKET SURVEILLANCE OF MEDICAL DEVICES

Philip D. Neufeld
Medical Devices Bureau
Therapeutic Products Directorate

CAPHC Patient Safety Workshop
Calgary, June 14, 2003

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MANDATORY PROBLEM REPORTING

**Manufacturers are required by Regulations to report
serious incidents to Health Canada.**

A 'serious incident' is one that

- is related to device failure, malfunction or labelling deficiency, and
- has led to death of a patient, or serious deterioration in health, or could do so if it were to recur

MANDATORY PROBLEM REPORTING

Manufacturer and distributor must submit preliminary and final reports

Health Products and Food Branch Inspectorate monitors manufacturer's corrective actions



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CLASSIFICATION OF MEDICAL DEVICES

Devices are classified into four categories related to potential risk.

Examples:

- **Class I: Surgical instruments, beds, thermometers**
- **Class II: IV tubing, blood bags**
- **Class III: X-Ray machines, external defibrillators, most implants**
- **Class IV: Implanted pacemakers and defibrillators**



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MANDATORY PROBLEM REPORTING

Mandatory Problem Reports

YEAR	Class I	Class II	Class III	Class IV
1999	79	146	115	146
2000	65	651	148	102
2001	41	680	220	130
2002	33	148	285	154



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VOLUNTARY PROBLEM REPORTING

- Reports are sent in by hospitals, physicians, or the general public
- Incident reports are entered into Health Canada's MDS Database
- MDB also has access to US FDA's MAUDE (Manufacturer And User Facility Device Experience) Database



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VOLUNTARY PROBLEM REPORTING

Health Canada's MDS Incident Database

- Database was started in 1978 and contains
 - Mandatory problem reports
 - Voluntary problem reports
 - Manufacturers' recalls
- Over 23,000 records
- 10,000 incident reports
- Searchable by manufacturer, device trade name, device type, dates, problem, etc.



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VOLUNTARY PROBLEM REPORTING

Voluntary Reports Since New Regulations, 1999

YEAR	Class I	Class II	Class III	Class IV
1999	53	71	28	22
2000	71	76	60	19
2001	50	82	63	58
2002	61	173	82	43



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HEALTH HAZARD EVALUATIONS

- **MDB reviews incident reports**
- **Evaluators assess risks and suggest corrective action**
- **Recommendations sent to Inspectorate for action**



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LABORATORY EVALUATIONS

- **Device samples are tested and evaluated in MDB labs**
- **MDB also conducts research on issues such as**
 - biocompatibility
 - electrophysiology
 - electromagnetic compatibility



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REGULATORY OPTIONS

- **Negotiate with manufacturer to find solution**
- **Revoke licence**
- **Stop sale**
- **Ban importation**



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NON-REGULATORY OPTIONS

- **Manufacturer's advisory to users**
- **Health Canada advisory to users**
- **Health Canada press release**



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ADVISORIES TO HEALTH PROFESSIONALS

- **Posted on the TPD website at**
- http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_professionals_e.html#2002
- **Readers can subscribe to receive e-mail updates of new postings**



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ADVISORY ON STRANGULATION RISK OF IV TUBING

- **Posted on the TPD website July 30, 2002**
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/iv_tubing_e.html
- **Health Canada received 5 or 6 responses from health care facilities.**
- **All were critical of first recommendation – continuous monitoring of children on IV.**



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The Marketed Health Products Directorate (MHPD), Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD) posts safety alerts, public health advisories, press releases and other notices from industry as a service to health professionals, consumers, and other interested parties. Although MHPD, TPD and BGTD approve therapeutic products, MHPD, TPD and BGTD do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

NOTICE TO HOSPITALS

**from the Marketed Health Products Directorate,
Therapeutic Products Directorate and the Health Products and Foods Branch Inspectorate**

July 30, 2002

To: Hospital Chief of Medical Staff

Please distribute to the relevant Departments of Anaesthesia, Intensive Care, Emergency, Nursing, Pediatrics, Surgery and other involved professional staff and **post this NOTICE** in your institution.

Risk of Strangulation of Infants by IV Tubing and Monitor Leads

Health Canada is concerned about reports of suffocation and death in young children caused by entanglement in IV tubing when children are treated in hospital. Young children are at risk of strangulation from any type of cord, whether these are consumer products such as blind cords, or medical devices such as electronic leads or IV tubing. Leaving a child unattended in any environment where entanglement with a cord, tube, or lead is possible may have disastrous consequences.

Health Canada recommends the following:

1. All hospitalized children who could possibly become entangled in a lead or tubing should be continuously observed by an adult or placed on a monitor.
2. Consider treating hospitalized children with oral therapy, or a heparin-locked needle if possible.
3. Coil excess tubing when the child is unattended to prevent the infant/child from becoming entangled.
4. Inform hospital staff, parents, and other care-givers that young children are at risk of entanglement and strangulation by IV tubing, electronic leads, or cords of any sort.

Health Canada asks that you share these recommendations with your staff or membership and encourage their implementation in the interest of patient safety.

If you have any concerns, problems or complaints pertaining to medical devices, you may report them to Health Canada at the address below, or through a toll-free **Hot Line at 1-800-267-9675**.

Health Products & Food Branch Inspectorate
Health Canada
Tower "A", Holland Cross
11 Holland Ave.
Address Locator: 3002C
Ottawa, Ontario K1A 0K9