

PAEDIATRIC REVIEW COMMITTEE
Final Report

NAME: Lisa Shore
CASE NUMBER: 12799/90
DOB: November 20, 1987
DOD: October 22, 1998

REVIEWED: March, 1999
November 20, 1999
January, 2000

Sources Reviewed:

1. Registered Coroner's Letters.
2. Correspondence from family and lawyer.
3. Hospital for Sick Children's chart.
4. Post Mortem Examination.
5. Coroner's Report.
6. ECRI Evaluation Reports
7. Inquest Brief
8. Toxicology Report (McLeod November 5, 1999)
9. PM Review of myocardial slides - report Dr. Charles Smith November 1999
10. HSC Report - November 10, 1999 letters S. Bauer
11. Dr. Schily Report (October 22, 1998)
12. Nurse Educator Report (Borden & Elliot) (Mary Douglas)
13. Preliminary testimony, November Inquest - S. Bauer
14. Boston Children's Hospital Chart
15. Meeting - Lawyer - Borden & Elliott (December, 1999)
16. Biopsy Analysis Report (December 17, 1999)

Background:

This 10 years and 11 months old girl was admitted to HSC Emergency Department at 21:51 on October 21, 1998 for severe right leg pain. The leg pain related to a nondisplaced spiral fracture of the right tibia which had been broken on February 11, 1998, while playing on the schoolyard. This was treated by closed reduction at the North York General Hospital. Lisa had several hospital visits and admissions, related to a complex pain syndrome which was a sequela.

The first post-fracture hospital visit was February 13, 1998 when she presented to HSC ER with severe right leg pain. The pain was relieved by splitting the cast. The cast was replaced at HSC Orthopedic Clinic on February 17, 1998.

She was admitted to HSC on February 24, 1998 for management of increasing right leg pain. This included PCA morphine, with a dose of 11 mg over 4 hours. She was discharged from that admission on March 6, 1998 but returned with severe pain on March 15, 1998. Discharge for that admission was on March 25, 1998.

During these two hospitalizations Lisa had assessment by the Pain Management Program and Psychiatry.

An assessment by the Toronto Hospital Comprehensive Pain Program on March 30, 1998 concluded that, "although [Lisa] may have had a neuropathic pain injury, her present pain pattern is highly non-physiological".

Her pain continued and parents took her to Children's Hospital in Boston for further evaluation and management. She was evaluated there by the Pain Treatment Service on May 13, 1998. A diagnosis of **reflex sympathetic dystrophy (RSD)** was made (complex regional pain syndrome type I) based on her allodynia, the coarse hair growth, the color changes and the osteopenia of her leg.

She was subsequently admitted to hospital in Boston on May 18, 1998, and returned again in September. During the first admission, she received a variety of attempts at pain control and eventually obtained some relief from a right lower extremity intravenous regional sympathetic block. She was discharged (May 22, 1998) with prescriptions for gabapentin 300 mg tid and amitriptyline 50 mg qhs, and recommendations for physical and behaviour therapy. A letter from the Behavioural Medicine Clinic of Children's Hospital in Boston noted Lisa's "medical and physical therapy examinations were consistent with a diagnosis of RSD and her psychiatric evaluation was benign."

Past medical history includes a tonsillectomy and adenoidectomy in April, 1998 and emergency appendectomy in September, 1997.

Final Admission

Lisa and her mother presented to the Pain Management Clinic, October 9, 1998, for the first time since March, and were requesting that care be provided through the clinic, with transfer from the Boston Children's which had been prescribing meds until then. A baseline review was carried out, and lab and ECG completed. (ECG and QTc normal, amitriptyline level normal.)

In HSC ER on October 21, 1998 Lisa was seen by the Pain Management Team. She was given morphine (2 mg at 23:50, October 21, 1998 and 2 mg at 00:40, October 22). An IV line was placed and a PCA device attached. The device was loaded with 50 mg morphine in 50 ml saline (1mg of morphine/ml of saline) and set to give 1.5 mg boluses with a lockout interval of 6 minutes and total dose 20 mg in

2 hours. At 22:00 hr her B.P. was 110/60, at 23:50, HR was 88, with RR 16, pain score 8/10. At 00:40, HR was 90, RR 14, BP 106/84 pain 7/10. She was supposed to be transferred from ER when pain control was 5/10, but the mother said this would not occur until she was asleep "upstairs". The treating resident was contacted, and she was transferred at 01:45. I.V. was at 20 ml/hr.

Lisa arrived on Ward 5A from ER at 01:45 October 22, 1998. She was noted to be in no obvious pain. Her vital signs were HR 72, RR 16 and BP 90/60. Her medications included Gabapentin 400 mg, 400mg, 600mg, Carbamazepine 200mg bid and Amitriptyline 75 mg. qhs.

She settled to sleep as soon as she was put on the bed. Mother stayed overnight at her bedside. At 02:50 her respiratory rate dropped to 8 to 10. The Pain Management on call person was paged by the nurse, who removed the analgesic delivery button from Lisa. The doctor on call did not respond, according to the nursing notes, but he indicated he received no page from the ward until 4 am. At 03:20, the HR was noted to be 120 and Lisa remained tachycardic throughout the remainder of the night (5 readings) (see Appendix i: Vital Signs chart/graph). Lisa appeared to have slept through the night, except for when she was aroused to have vital signs taken. At 4:05 the covering nurse called the doctor on call because the respiratory rate was depressed, and he told her to remove the PCA button, which had already been done. He later reported (in the HSC response letter) that he was told her vitals were stable. Her respiratory rate recorded at 06:00 was 14 and her heart rate was 126. At 04:15 the chart indicates a respiratory rate of 10 but at 04:20 the rate had increased to 16.

The Orthopedics team found Lisa's vital signs absent during their morning rounds at 07:15. Full resuscitation commenced including intubation (6.0 ETT), Narcan (3 doses), Epinephrine (7 doses) Bicarb (2 doses) Atropine (1 dose). No cardiac output resulted after 30 minutes and the resuscitation was stopped.

Post Mortem Results:

1. Pulmonary congestion and edema, moderate.
2. Cerebral edema, mild with:
 - A. No other neuropathological diagnosis.
3. Toxicologic studies, with:
 - A. Blood concentration of morphine (105 ng/mL) "within therapeutic range".
 - B. Blood concentration of gabapentin (1.1 mg/100mL) in excess of therapeutic range.
 - C. Blood concentration of carbamazepine (0.39 mg/100mL) below therapeutic range.
 - D. Blood concentrations of amitriptyline (traces) and nortriptyline (0.01 mg/100mL) within therapeutic range.

- E. No other significant findings by drug screening procedure.
- 4. Manifestations of mild intercurrent viral infection, with:
 - A. Lymphocytic laryngotracheitis, moderate.
 - B. Lymphocytic triaditis of liver, mild.
 - C. Sparse myocardial lymphocytes without myocyte necrosis.
- 5. Acute pneumonia, focal, slight.
- 6. Esophagitis consistent with gastroesophageal reflux injury, mild.
- 7. Chronic antral gastritis, mild.
- 8. Status post appendectomy, remote, with:
 - A. Peritoneal adhesions, right lower quadrant, mild.

Comments:

"An anatomic cause of death is not identified at autopsy examination. Detailed toxicologic analysis of blood and solutions from the infusion apparatus did not disclose drug concentrations that could be reasonably implicated as cause for this child's death. In particular, the blood morphine concentration was within the reported therapeutic range for patients taking the drug for management of chronic pain. The gabapentin concentration was well in excess of the reported therapeutic range, however, serious toxicity is not identified with blood concentrations even 5 times higher than found in this child. The child had evidence of an underlying viral infection, with lymphocytic infiltrates in the upper respiratory tract, liver and sparsely in the heart, but this is also not sufficient to satisfactorily explain the sudden death.

Cause of Death:

No anatomic or toxicologic cause of death identified."

Because of concerns raised by the Paediatric Coroners Review committee, and the toxicology expert, a PM review of the significance of the "sparse myocardial lymphocytes without myocyte necrosis" was carried out. The review opinion concluded, "there is no morphologic evidence to support a diagnosis of myocarditis". Further, myocardial tissue was forwarded for viral examination and the results were negative for enteroviral RNA. The conclusion was "this strongly suggests that the sample was not infected with enterovirus".

Issues for Paediatric Coroners Review Team:

1. No cause of death identified:

The committee noted that the clinical history suggested a respiratory depression leading to cardiac arrest, or cardiac arrest secondary to an arrhythmia. The gabapentin level was elevated, while the morphine level was in the "therapeutic" range. The ECRI pump review showed the delivery system to be functioning with appropriate drug concentrations in use. The Paediatric Coroner's Review Committee initially had a number of questions with regard to the possible interaction of the gabapentin with other medications (i.e. morphine), the applicability of the quoted drug studies to children, the child's previous experience with these medications in combination, the respiratory depression noted and its relationship to these medications etc.

These questions were addressed by the toxicology expert opinion which concluded "I do, however, think it is likely that death was caused by a cardiac conduction disturbance which may have resulted from a complex interaction among the therapeutic drugs, the patient's physical condition and a concurrent viral infection."

Further, the significance of the concurrent viral infection was reviewed.

OPINION:

The Review committee did not feel there was sufficient evidence to determine the cause of death. A number of theories were discussed and explored including "some complex drug interaction, as yet undescribed", but no cause was confirmed from the evidence reviewed.

2. Monitoring of Lisa while on Ward 5A, on a PCA morphine:

Although the initial committee review concentrated on the contents of the Family letter of 24 questions (December 11, 1998) in 9 areas * mailed to the Regional Coroner, most of these questions were clarified through subsequent letters of explanation from the HSC, inquiry of the Coroner's office and other written statements.

****The 9 areas were: Corometric monitor, application? Capacities – memory, alarm protocols and orders for use; tachycardiac – interpretation and notification respiratory rate – the change, monitoring and recording;***

protocols – use and physician notification; Death summary inaccuracies (total morphine dose, Lisa being awakened); Hypoventilation –physician response, nursing interpretation; PCA pump – time discrepancy regarding removal; Nursing recording;? previous similar deaths.

The appropriate monitoring of Lisa should have included compliance with the physician orders (written and KIDCOM) which are outlined in Appendix ii – Chart of physician orders for monitoring. Although the hospital has undertaken substantive review and training of staff about the content of these orders subsequently, the review with respect to this case indicated that:

- a) The Kidcom orders were not read/opened on admission to the ward, or during the night: the committee recommends that HSC investigate the frequency with which orders are not accessed from the KIDCOM system and the average delay between children being admitted and the orders being accessed. The Protocol (June, 1994) for KIDCOM orders (admission from Emerg.) indicates the resident in ER should telephone notify the unit of KIDCOM admission orders. In this particular case, the physician had clearly handwritten on the ER sheet about the existence of the KIDCOM orders, although he did not notify the ward by phone.
- b) The monitoring of Lisa did not include the ordered frequency of vital signs, or pain and sedation scales, BP, oximetry. (see appendices i, ii)
- c) Even though the monitoring was insufficient, that which was done demonstrated cause for clinical concern. The response to this monitoring by nursing staff was insufficient in the opinion of the committee- the tachycardia and the falling respiratory rate required timely medical attention. Although the physician on call was paged, according to the nurses (2:50 a.m.), when he did not respond, a repeat call should have been made in a timely fashion, or the other on call alternatives pursued (Staff person, OR desk), as outlined in the KIDCOM orders reviewed.

The nurse eventually spoke with the physician (4:30 a.m.), after the PC button was removed. The Committee reviewed the reported conversation (Schily record October 22, 1998) between the physician and the nurse "at about 4:00". He reported the nurse saying "all vital signs are good". The Committee felt his response to the information he reported receiving, was appropriate.

- d) The use of the Corometric monitor: Electronic monitoring is an important adjunct to the nursing care provided to children in hospital. The statements reviewed by the committee indicated that the monitor was not appropriately used – the apnea alarm was turned off; the monitor did

not appear to be turned on at the time of death (statements reviewed from the physician who arrived on the morning of the arrest indicate the monitor was turned off, the mother's statement indicated that the monitor was not on, and the nursing educator noted the monitor was off when she arrived at the arrest). Further, the monitor failed to alarm when the leads were removed at the time of the resuscitation.

Final Conclusion:

The committee supported the move to Inquest

VITAL SIGNS CHART / GRAPH

Heart Rate	Resp Rate
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—■— Respiratory Rate
- - □ - - Heart Rate

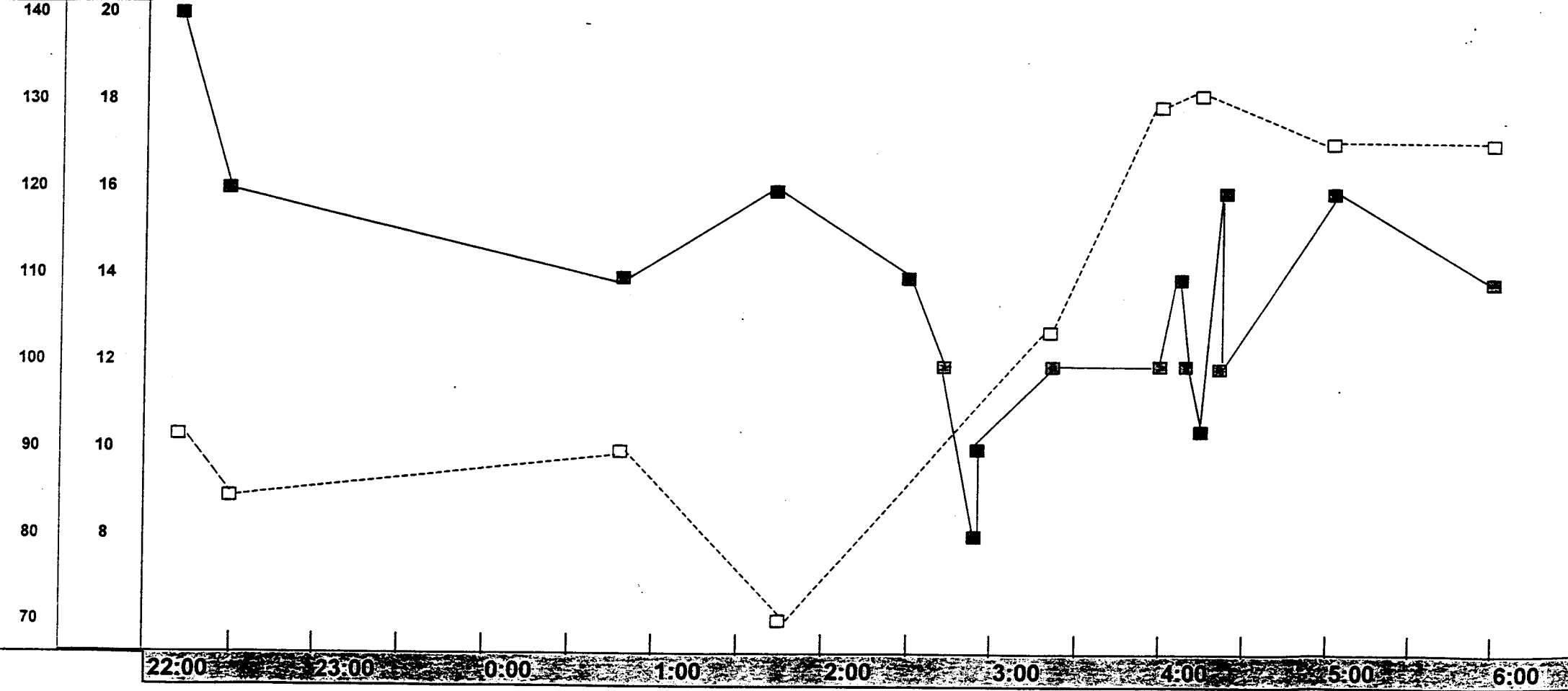


Chart of Physician's Orders for Monitoring on Ward 5A

LAPSED TIME	REAL TIME	TEMPERATURE	PULSE	RESPIRATION	BLOOD PRESSURE	SEDATION SCALE	PAIN SCALE	OXIMETRY
0	1:45	✓	✓	✓	✓	✓		
	2:30			✓				
1	2:45			✓				
	2:50			✓				
	3:20		✓	✓				
2:15	4:00		✓	✓				
	4:05			✓				
	4:15		✓	✓				
	4:20			✓				
3:15	5:00	✓	✓	✓				
4	6:00		✓	✓				
5	7:15							

KEY

Physician's Order

✓ Carried Out