GERIATRIC AND LONG-TERM CARE REVIEW COMMITTEE

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Name of deceased:	(decedent 1)
Date of death:	September 18, 2018
Age:	87 years
OCC file number:	2018-13465 (GLTCRC 2021-7A)

Name of deceased:	(decedent 2)
Date of death:	August 15, 2018
Age:	96 years
OCC file number:	2018-11842 (GLTCRC 2021-7B)

Name of deceased:	(decedent 3)
Date of death:	May 10, 2018
Age:	92 years
OCC file number:	2018-6617 (GLTCRC 2021-7C)

Reason for review:

These cases involved elderly individuals with cognitive impairment who died after falls from their power recliner lift chairs. In all three cases, the individuals accessed the remote-control unit for the power-lift chair they were sitting in and were able to raise the seat to elevate them into a standing position. Once elevated, the individuals fell and suffered injuries that lead to their deaths.

Decedent 1 - 2018-13465 (GLTCRC 2021-7A)

Documents for review:

- Coroner report
- Hospital records
- Family physician records

History:

The decedent was an 87-year-old man with a medical history that included: dementia, seizure disorder, atrial fibrillation with pacemaker (presumed Sick Sinus Syndrome), hypertension, colitis, bladder stones and right hip fracture with total hip arthroplasty (April 2015 after falling while being assisted out of a car).

His medications included: clonazepam, metoprolol, potassium, furosemide, Senokot, Dilantin, clopidogrel, Ventolin, acetylsalicylic acid (ASA), pantoprazole and vitamin D.

The decedent lived at home with his wife who was his primary caregiver and a personal support worker (PSW) provided assistance two times a week. The man could speak short phrases and answer 'yes' and 'no.' He was wheelchair dependent for ambulation and spent much of his day in a power recliner chair that would raise him into the standing position at the push of button. The chair had a remote control connected by an electrical cord. The decedent enjoyed the chair and preferred to sleep in it.

According to a family member, in 2014 or 2015, the man suffered a fall out of the chair. Apparently, he got ahold of the controller and engaged the chair. After being lifted to the standing position, the man fell, but was not injured. Following that incident, the decedent's wife moved the controller to make it more difficult for him to access and activate on his own.

On September 17, 2018, the decedent was sitting in his lift chair and his wife was in another room. His wife heard a thump and found her husband lying prone on the floor in front of the chair with his head to the side. The chair was in the up/standing position. The man's family placed him back in the chair and noted right thumb and shin abrasions; he also indicated that he had significant right knee pain.

Emergency medical service (EMS) were notified and the man was taken to hospital where he was diagnosed with a right distal femur fracture. He received two doses of subcutaneous hydromorphone (0.5 mg at 0115 hours and 0.5 mg at 0135 hours on September 18, 2018).

At approximately 0200 hours, his leg was placed in a cast and he was admitted to the orthopedics ward at 0300 hours

At 0525 hours, he was found without vital signs. A 'do not resuscitate' (DNR) order was in place and the man was pronounced deceased.

A postmortem examination was not done. Cause of death was noted as complications of femur fracture.

Decedent 2 - 2018-11842 (GLTCRC 2021-7B)

Documents for review:

- Coroner's investigation statement
- Long-term care home (LTCH) records
- Hospital records report, LTC records, hospital records

History:

The decedent was a 96-year-old woman with a medical history that included severe Alzheimer's disease, osteoporosis, diabetes (type 2), hypertension, and a complex left hip fracture (in 2014 requiring two surgical revisions and eventual surgical union).

Medications included: hydromorphone, furosemide, citalopram, calcium, vitamin D and acetaminophen.

The woman lived in a LTCH where she required total care for all her activities of daily living (ADLs). She required a wheelchair for mobility. The woman did not speak much but could answer 'yes' and 'no.'

At 1410 hours on August 5, 2018, the woman was found lying on her right side in front of her power recliner. Her roommate called nurses after her fall. Notes from the facility indicated that the woman "pushed the remote button which lifted the chair up." Further details of the incident are sparse. Presumably, the chair lifted the woman into a standing position and she subsequently fell. She was transported to hospital where she was diagnosed with a right intertrochanteric hip fracture. The on-call orthopedic surgeon had a discussion with the family and the decision was made not to proceed with surgery.

The woman was transferred back to the LTCH and treated palliatively.

Her condition declined and she died on August 15, 2018.

A postmortem examination was not done. Cause of death was noted as complications of right hip fracture.

Decedent 3 - 2018-6617 (GLTCRC 2021-7C)

Documents for review:

- Coroner investigation statement
- Retirement home records
- Hospital records
- Police records
- Postmortem examination report

History:

The decedent was a 92-year-old man with a medical history that included mild dementia, frequent falls, hypothyroidism, and hypertension. He lived independently in a retirement home (RH) and his family helped him frequently. He took most meals in the communal dining room of the facility.

Medications included eltroxin, perindopril and acetaminophen.

The decedent ambulated independently and often slept in his recliner. He had several falls and history suggested that he did not always inform staff at the RH when he fell.

In 2015, he fell and suffered an odontoid fracture; the mechanism of the fall was not listed in the medical notes. In December 2015, he scored 19/30 on a MoCA assessment.

On April 4, 2018, he was transported to hospital after losing his balance and falling on his right side and scraping his forehead. A CT scan of the head showed no acute findings.

On April 5, 2018, a visit from an occupational therapist (OT) found that the man had experienced several falls over the previous three months; he was unable to state how many of the falls occurred and did not always report the falls to the RH staff. The man used a rollator walker at the time and the OT recommended personal support, homemaking, and physiotherapy.

At 0530 hours on May 10, 2018, a laundry attendant at the RH found the man prone on the floor of his locked apartment in front of his recliner. There was a pool of blood near his head.

EMS were called and upon response, determined that the man was deceased. The recliner chair was found in the standing position.

Police attended and did not suspect any foul play.

Postmortem examination:

Following an autopsy, the cause of death was determined to be blunt force head trauma with cervical spinal fracture at C2 and cervical spinal cord compression.

Discussion on the three cases:

Decedent 1 was a frail man with dementia who died after accessing the remote control unit of his power recliner and engaging the mechanism to put him into the standing position. The remote unit was usually hidden behind the chair by his caregiver, who was in another room at the time of the fall. After being lifted by the chair, he fell to the ground and suffered a hip fracture; he subsequently died from complications of injuries sustained in the fall.

Decedent 2 was a frail, chair-bound 96-year-old woman with severe dementia who lived in a LTCH. She had an unwitnessed fall after engaging her power chair mechanism. She subsequently died from injuries sustained in the fall.

Decedent 3 was a capable 92-year-old man with cognitive impairment and a history of falls who lived independently in a RH. He was found alone on the floor of his apartment in front of his power recliner that was in the upright position. It is believed that he was lifted by the chair, then fell to the ground. He suffered a head injury and fatal cervical spine fracture.

Similarities in the cases appear to be:

- All three decedents were elderly.
- All had cognitive impairment.
- All spent long times sitting or sleeping in their power recliner chairs.
- All had access to the remote control mechanism that engaged the chair to lift them into an upright position.
- All had unwitnessed falls after activating their chairs, being lifted to a standing position and then falling to the ground and sustaining injuries.
- None of the chairs were apparently evaluated or "approved" by health professionals. All three of the chairs involved appear to be older and discontinued models.
- Medication did not appear to impact the likelihood of falls.

Dissimilarities between the cases include:

- The incident locations included a private residence, a LTCH and a retirement home.
- Two of the decedents had a documented history of falls.
- The degree of cognitive decline varied with one decedent having mild and two with severe impairment.
- The model and manufacturer of the power recliner chairs were all different.
- Injuries varied from hip fractures to a cervical spine and head injury.

Power-lift chairs:

Decedent 1 used a Pride Brand chair. The chair involved appears to be an older model and is no longer manufactured. The company's 2020 website instructions advise users to, *"Keep the hand control locked or utilize the quick-disconnect feature on the standard hand control when the chair is not in use to prevent unintended operation of the chair. Store the hand control in the side pocket of your chair when not in use."*

Decedent 2 used the Capri by Golden Technologies. The company website indicates that, *"This power lift and recline chair is a medical device designed to help you sit down and stand up. Do not allow children to operate the chair at any time. When not in use, the chair should be kept in the sitting position. Do not operate this product if you have any medical conditions that result in limited, debilitating mental or physical capacity. You should consult your doctor before using this product."*

Decedent 3 used the Best Home Furnishings - Best Chairs Inc. - Power Lift Recliner. Specific instructions or warnings were not noted on the company website. A photo of the remote device indicates a unit with a simple up/down mechanism.

There is little literature on deaths related to falls after being elevated from power-lift chairs. There does not appear to be any case reports in the medical literature of similar falls although it appears that these incidences represent a potential danger to the elderly, the mobility challenged, and the cognitively impaired. Although Canadian data could not be found, the United States Consumer Product Safety Commission indicates that for "87 million American households, an estimated 24 million households have recliner chairs in them."

Regulatory framework:

The *Canada Consumer Product Safety Act* and the *Canada Food and Drug Act* appear to be the two regulatory frameworks in Canada that are responsible for safety monitoring of power-lift recliner chairs.

The *Canada Consumer Product Safety Act* (under Health Canada) was created to "protect the public by addressing or preventing dangers to human health or safety that are posed by consumer products in Canada, including those that circulate within Canada and those that are imported." The act allows for a recall or protective measure to ensure public safety.

Appendix 1 provides additional detail on relevant sections of the Canada Consumer Product Safety Act.

The Canada Consumer Product Safety website (https://www.canada.ca/en/health-canada/services/consumer-product-safety/legislation-guidelines/acts-regulations/canada-consumer-product-safety-act.html) allows search of their database for reports on unsafe devices. A review of this site did not identify any product recalls or safety alerts for lift chairs, recliner chairs, or recliner power chairs.

In a similar US database maintained by the Consumer Product Safety Commission (CPSC), there were multiple recalls related to entrapment and injury of children from power chairs. Designers have added innovative safety features to avoid such injuries. One product states that, "Our Anti Entrapment feature …is designed to stop the chair from travelling if it comes into contact with any other object."

Of the millions of recalls of products on the US database, only one involved a recliner lift chair. The chair involved in that recall had a "joystick reclining mechanism" that could malfunction. This chair and type of mechanism was not involved in the cases reviewed by the GLTCRC.

The Canadian legislation regulating medical devices is the *Food and Drug Act*. Recliner chairs are considered *medical devices* under the Food and Drug Act - Medical Devices Regulations. Medical devices are classified in four groups with level one being the least invasive, and level four the most. A power recliner chair falls into class two. Class two devices such as power wheelchairs and recliner chairs represent 43% of all medical devices and are considered moderate to high risk to patients. All devices, other than class one, must be licensed before importation into Canada.

According to the Food and Drug Act, S. 59 (1) of the Medical Devices Regulations (see Appendix 2), outlines the mechanism for reporting potentially unsafe medical devices.

This legislation appears to be a powerful tool to report incidents involving potentially unsafe medical devices and includes the requirement for manufacturers to provide a response on how the concerns will be addressed.

Recommendations:

To the Office of the Chief Coroner (OCC):

1. It is recommended that the relevant Regional Supervising Coroner report these three incidents to the federal government through the Canada Consumer Product Safety Act online portal (https://www.healthycanadians.gc.ca/apps/radar/CPS-SPC-0001.08.html)

To Health Canada:

2. Health Canada should encourage manufacturers to consider principles of Accessible and Universal Design for products being utilized by elderly patients and cognitive differences, in the same way child safety has been prioritized. Best practices should be established for categories of products such as power recliner chairs to help manufacturers design safer products

To the manufacturers, distributors and retailers of recliner chairs, through Health Canada:

3. Manufacturers of power lift chairs should consider lockout mechanism or mechanism to unplug the remote controller to restrict access to cognitively impaired individuals.

4. Manufacturers of power lift chairs should improve their website and consumer information. The risk of falls must be emphasized in print and internet literature. Also, literature should include warnings for elderly with cognitive difficulties.

To the Ministry of Long-Term Care, Long Term Care Association and Retirement Homes Regulatory Authority:

5. Long-term and retirement homes should ensure that all medical devices used within their facilities meet safety standards and appropriately reflect the cognitive and physical needs of the resident they are assigned to. This will include ongoing monitoring of the devices and any recall or safety notices issued, as well as ongoing monitoring of the resident's need and ability to safely use to the device.

6. Long-term and retirement homes should report concerns with any medical device to Health Canada through their online reporting portal.

To the College of Occupational Therapists, College of Nurses, College of Physicians and Surgeons and Health Shared Services Ontario:

7. Lift or recliner chairs should be included in home assessments with consideration of safety in patients with cognitive decline.

References:

Mustaquim, Moyen. A Study of Universal Design in Everyday Life of Elderly Adults. Procedia Computer Science 2015; 67; pp 57-66.

Center for Accessible Housing. Accessible environments: Toward universal design. Raleigh: North Carolina State University; 1995.

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Milbank Quarterly. 2005 Dec; 83(4); pp 401-28.

Appendix 1

Excerpt from Canada Product Safety Act

Section 14

(1) In this section, ***incident*** means, with respect to a consumer product,
(a) an **occurrence in Canada** or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;
(b) a **defect** or characteristic that **may reasonably be expected to result in an individual's death** or in serious adverse effects on their health, including a serious injury;
(c) incorrect or **insufficient information on a label** or in instructions — or the lack of a label or instructions — that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury; or
(d) a recall or measure that is initiated for human health or safety reasons by
(i) a foreign entity,
(ii) a provincial government,
(iii) a public body that is established under an Act of the legislature of a province,
(iv) an aboriginal government as defined in subsection 13(3) of the *Access to Information Act*, or
(v) an institution of an entity referred to in subparagraphs (ii) to (iv).

Requirement to provide information

(2) A person who manufactures, imports or sells a consumer product for commercial purposes shall provide the Minister and, if applicable, the person from whom they received the consumer product with all the information in their control regarding any incident related to the product within two days after the day on which they become aware of the incident.

Report

(3) The manufacturer of the consumer product, or if the manufacturer carries on business outside Canada, the importer, shall provide the Minister with a written report — containing information about the incident, the product involved in the incident, any products that they manufacture or import, as the case may be, that to their knowledge could be involved in a similar incident and any measures they propose be taken with respect to those products — within

10 days after the day on which they become aware of the incident or within the period that the Minister specifies by written notice.

Appendix 2

Excerpt from Food and Drug Act
Medical Devices Regulation

https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-7.html#h-1021831

59 (1) The manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring in Canada that involves the device if

(a) the device is sold in Canada; and

(b) the incident

(i) is related to a failure of the device or a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use, and

(ii) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur.

(1.1) Subject to subsection (2), the manufacturer and the importer of a Class I medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring outside Canada that involves the device if the conditions in paragraphs (1)(a) and (b) are met.

(2) The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action.

60 (1) A preliminary report shall be submitted to the Minister

(a) in respect of an incident that occurs in Canada

(i) within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or

(ii) within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and

(b) in respect of an incident that occurs outside Canada, as soon as possible after the manufacturer has indicated, to the regulatory agency referred to in paragraph 59(2), the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.

(2) The preliminary report shall contain the following information:

(a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

(b) if the report is made by

(i) the manufacturer, the name and address of that manufacturer and of any known importer, and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident, or

(ii) the importer of the device, the name and address of the importer and of the manufacturer, and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident;

(c) the date on which the incident came to the attention of the manufacturer or importer;

(d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;

(e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;

(f) the identity of any other medical devices or accessories involved in the incident, if known;

(g) the manufacturer's or importer's preliminary comments with respect to the incident;

(h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report; and

(i) a statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report.