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Update Report

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Insulin Pumps Linked to Reports of Injury and Death

"What's your birth date?" "November ... November ... 27... November 27, 1963," says Christine Landry, her voice fading over the phone. The 49-year-old registered nurse from Cornwall, ON, sounds tired and confused. It's the night of July 22, 2012, and Landry called a 24-hour helpline run by Medtronic, the company that manufactured her insulin infusion pump, because a button on her device was stuck and making a loud beeping sound.

On a recording of the conversation, she can be heard struggling to answer basic questions as she arranges for a replacement pump to be delivered to her home. The next morning, her son, Philippe, then just 20 years old, found her unconscious in her bed. His mother did eventually wake up, but with severe brain damage. She died this past September. Like millions of people with diabetes around the world, Landry used an insulin infusion pump to try to improve her quality of life.

A CBC News/Radio-Canada/Toronto Star investigation finds that for some people with diabetes, depending on their level of training and knowledge, the popular device might not be the safest way to regulate their blood glucose levels.

Health Canada data obtained under Access to Information reveals that in the past ten years, insulin pumps have been the subject of at least 40 recalls and may have played a role in 103 deaths and more than 1,900 injuries — more than any other high-risk medical device in the health agency's database. The records did not include any information on how many pumps are currently used in the country. In a statement, Health Canada said that's because "it does not require manufacturers to provide sales numbers for medical devices".

The pump performs some of the functions of a healthy pancreas, slowly dripping insulin through a tube and needle under the skin, helping a person with diabetes to control their blood sugar levels.

Pumps were first approved in Canada in the early 1980s and have become increasingly high-tech. Manufacturers and provincial governments consider pumps so safe and simple to use, they are recommended and insured for children.

Many people with diabetes say insulin pumps are convenient and provide them with more control over their blood glucose levels than the traditional syringe or pen methods. The pump uses only rapid-acting insulin, which means the user can have worry-free meals and snacks at the touch of a button. The pump's constant drip of insulin can also help with the so-called dawn phenomenon, a potentially dangerous surge in blood sugar in the early morning.

But some doctors warn the convenient device requires considerable knowledge and skill to be used safely and effectively. Dr. Peter Senior, an Edmonton-based endocrinologist who has done

consulting work for pump makers, says the devices can be life-changing, but only for people with diabetes who have learned to manage their blood sugar levels. Senior points out Type 1 diabetes carries life-long risks regardless of how people with the condition choose to receive their insulin.

Dr. Senior estimates that as many as 10 per cent of Type 1 diabetics are using an insulin pump, which could amount to 30,000 Canadians. In the U.S., it's now 40 per cent.

Dr. Simon Heller runs a five-day course for people with Type 1 diabetes in the U.K. As part of a study, the professor of clinical diabetes at the University of Sheffield gave a group of 317 insulin pump and needle users the same training and compared their glycemic levels and quality of life over time. "One of the reasons we did this trial," he said, "is that we are concerned that people might use the pump expecting the pump to fix them."

His two-year study, published in the British Medical Journal, found that after both groups completed intensive training on insulin management, participants using pumps reported only a slightly better quality of life than those using needles. He found that increasing a person's understanding of how to manage their condition is just as important as technology.

In 2010, Health Canada actually closed its Bureau of Medical Devices labs to cut costs. Briefing notes sent to Health Minister at the time, and obtained by CBC News, show the department was under pressure to approve licences for a growing number of medical devices. To pay for that work, cuts had to be made to "lab research in low-impact or non-critical areas."

In a statement to CBC, Health Canada said lab testing is now done by device manufacturers themselves or outsourced to third parties. "This is more cost-effective and allows the department to access state-of-the-art facilities across all areas, rather than maintain lab capacity related only to specific scientific domains."

Health Canada also said because of "recent post-market concerns" with all infusion pumps, including insulin pumps, it now requires manufacturers to submit evidence of more rigorous testing on their devices before they can be approved for sale.

Source: cbc.ca, November 2018 https://www.cbc.ca/news/health/implant-files-insulin-pumps-1.4915491

Other Countries Provide Pharmacare Lessons

As Canadian policymakers grapple with a potential national pharmacare program, lessons can be learned from the United Kingdom, Australia, and New Zealand where publicly-funded pharmacare schemes have resulted in reduced access to new drugs for patients, drug shortages, higher taxes, and less pharmaceutical innovation, says a study by the Fraser Institute.

"Government-run pharmacare programs in countries such as the UK, Australia, and New Zealand have produced unintended consequences for patients, so Canadians should be aware of the risks

as policymakers here pursue potential reforms," says Kristina Acri, professor of economics at Colorado College, Fraser Institute senior fellow, and author of 'The Unintended Consequences of National Pharmacare Programs in Australia, New Zealand and the UK.'

It finds that government-run pharmacare programs in all three countries employ similar strategies to contain costs. However, they can lead to:

- Reduced access to new drugs, as pharmaceutical companies delay or even withhold new drugs (in certain markets) if the price regulated by government is too low;
- Potential drug shortages, as government-funded pharmacare programs tend to favour single suppliers, leaving patients vulnerable to shortages if the sole supplier runs out;
- Higher taxes, as previous research estimates government-run pharmacare in Canada would cost taxpayers up to \$13 billion per year; and
- Less pharmaceutical innovation in Canada because when government mandates lower prices, there's less incentive for pharmaceutical companies to invest in research and development to create new life-saving drugs.

Source: bpmmagazine.com, December 2018 http://bpmmagazine.com/news/page/4/

Addressing the Social Needs of Older Adults

Humans are, by nature, social animals. No matter our age, we all have social needs – whether it's the need to be loved, to be accepted by our peers, or to belong to a community. Satisfying these social needs can improve your quality of life and help protect against illnesses and depression.

As we age, our social priorities and needs can change. They can also be more difficult to fulfill due to health problems, mobility challenges and a shrinking social network, which may contribute to the feelings of loneliness and social isolation experienced by many older adults.

A recent systematic review of 14 studies examined the social needs of people over 65 and identified ways to contribute to their well-being. This systematic review identified four main themes: 1) a diversity of needs; 2) the need for proximity; 3) the need for meaningful relationships; and 4) the need for reciprocity.

Research evidence reveals that not all older adults have the same social needs; there are individual and cultural differences. Some cultures may be more supportive of (and actively engage) their elders than others. Also, not everyone feels the need to have an extensive social network in order to be happy. It must be remembered that social needs are rooted in the personalities, desires, expectations and cultures of older adults.

As we age, our social network often becomes less extensive and the frequency of contact with friends and loved ones tends to decrease. While relationships with close friends or family members are important, relationships with neighbours and other members of the community

also play significant roles. Having a support network that is close by will contribute to older adults' feelings of safety, comfort and connectivity.

Meaningful social relationships help to provide affection, as well as a sense of purpose and respect. Research evidence shows the importance of social networks, which includes family, friends, neighbours and community members. Even casual conversations with strangers can fulfill some social needs of older adults. Older adults are generally afraid of becoming a burden to their friends and loved ones (or being perceived as such).

Reciprocity relates to both proximity and meaningful relationships: a relationship seems stronger when there is some reciprocity. Reciprocity means not only receiving from others, but also offering support and friendship, helping others and contributing to society (whether by volunteering or helping neighbours). Feeling useful is an important contributor to older adults' sense of independence and purpose.

In light of these findings, it is possible to draw some recommendations to address the social needs of older adults:

- Consider individual and cultural differences while developing and implementing interventions to address the social needs of older adults. Everyone does not have the same social needs.
- Encourage older adults to engage in volunteer activities that put their talents and expertise to work, which will nurture their sense of purpose and of belonging to a community.
- Focus should also be put on interventions that encourage older adults' social connections and engagement. Community hubs providing a central access point for a range of cultural and recreational programs and services (such as public libraries) can be particularly promising to address their need for meaningful relationships with people nearby.

Source: mcmasteroptimalaging.org, December 2018 https://www.mcmasteroptimalaging.org/blog/detail/blog/2018/12/05/addressing-the-social-needs-of-olderadults-a-contributing-factor-to-their-health-and-well-being

Tips for Facing Disasters

Be prepared: the Scouts' motto highlights their desire to be always ready to take action to deal with any situation. But being prepared to face disasters (natural or man-made) is not an easy task. Recent research on climate change and rapid urbanization predicts an increase in the intensity and frequency of natural disasters, including hurricanes, ice and snowstorms, floods, droughts and heatwaves. Older adults are particularly vulnerable to such disasters. But what does the research tell us about their ability to cope with and recover from disasters?

A systematic review of 33 articles examined the key factors influencing the capacity of older adults to cope with disasters (also known as 'resilience'). Seniors' resilience to disasters is a complex issue involving many factors ranging from individual characteristics (for example, health status, age, income, marital status, beliefs or prior exposure to similar stressful events) to social and organizational factors (for example, access to social support, access to health and social services, and access to information and communication channels).

Income is an example. We sometimes wonder why people living in flood zones do not move to a safer zone to avoid future floods. The reason may be as simple as not having the financial means to do so. Income also has an impact on how well people are able to recover from a disaster. Several studies show that low-income older adults are more likely to struggle financially and may be unable to rebuild their homes and their livelihoods. Low incomes can thus exacerbate the stress generated by a disaster.

Another factor is the level of social support of older adults. Social support has a certain influence before, during and after a disaster: all studies report a better response when older adults are well supported. The decision to evacuate is often made following discussions with relatives and neighbours. Having more social support means less depression, generalized anxiety disorder or post-traumatic stress following disasters. Also, being part of a community and helping with reconstruction help to shape a sense of belonging and purpose.

Communication channels commonly used to provide information during disasters often disadvantage older adults. The authorities responsible for public safety in case of disasters increasingly use social media like Facebook and Twitter, as well as digital television, as part of their information and alert systems. Research shows that these channels seem to be used to a lesser extent by older adults.

Finally, the health status of older adults is an important factor. Pre-existing health conditions often worsen after disasters, as older adults no longer have access to all the care they need (for example, lost medication, damaged medical devices, absence of support staff). In addition, studies show that authorities often implement evacuation or security procedures that are not always suitable for older adults, such as hiding under tables or requiring people to carry heavy equipment to build a dike. Older adults with mobility or cognitive problems will also have difficulty accessing emergency resources set up by the authorities.

Being prepared for a disaster or other emergency means at least four key elements:

- 1. Identify the risks in your area.
- 2. Prepare an emergency plan based on these risks and your own capacities (or if you live in a facility, find out about their emergency plan).
- 3. Prepare an emergency kit that will allow you to be self-sufficient during the first 72 hours of an emergency.
- 4. Form a personal support network of at least three people you know, trust, and can help in an emergency.

Source: mcmasteroptimalaging.org, December 2018 https://www.mcmasteroptimalaging.org/blog/detail/blog/2018/12/14/be-prepared-tips-for-facing-disasters

Thinking Outside the (Pill) Box

As people get older and suffer more age-related health problems, they're likely to continue adding to the collection of pill bottles on their night stand or pill shelf. Those medications were likely prescribed for good reason, but over time some drugs may no longer be helpful, and in fact can even cause harm. A doctor or pharmacist can help assess the benefits and risks of each one and "deprescribe" any that are no longer appropriate.

There is good evidence that alternative, non-drug options such as relaxation techniques (including music & yoga), exercise, acupuncture and cognitive behavioural therapy can provide relief for many common causes of pain and other ailments.

Here are five alternative therapies that have been tested by researchers:

- Acupuncture for headaches Headaches can affect your quality of life. Acupuncture may help reduce the frequency of headaches and migraines, at least in the short-term, and is safe and well tolerated.
- Tai chi for type 2 diabetes Traditional Chinese Medicine has been practiced for thousands of years and encompasses exercises like tai chi and ba duan jin. In people with type 2 diabetes, tai chi may help reduce fasting blood sugar levels and BMI, and improve certain aspects of quality of life; while ba duan jin may help lower fasting and average blood sugar levels and BMI, and improve symptoms of depression.
- Yoga for balance, low back pain and more The poses, stretches, breathing and relaxation/meditation techniques associated with yoga are credited with maintaining good health and improving health conditions that tend to affect us as we age. Yoga can help to relieve chronic low back pain, improve balance and mobility and ease symptoms of certain diseases such as cancer, asthma and type 2 diabetes.
- Music Music can promote well-being and a sense of control, reduce anxiety, improve memory, and build social connections.
- Exercise to reduce symptoms of depression Exercise can enhance mood and a sense of well-being due to endorphins and other "feel good" chemicals in the brain that are released when we're physically active. Exercise is prescribed often in combination with other therapies to help reduce symptoms of depression.

Source: mcmasteroptimalaging.org, December 2018 https://www.mcmasteroptimalaging.org/hitting-the-headlines/detail/hitting-the-headlines/2018/12/18/thinking-outside-the-(pill)-box

Canada's Food Safety Vulnerable during U.S. Shutdown

The quality of American food imports coming to Canada could be affected by the partial government shutdown, according to one food policy expert. Sylvain Charlebois, a professor in food distribution and policy at Dalhousie University is concerned about a disruption in regulatory oversight because of the shutdown's impact on the U.S. Food and Drug Administration (FDA). The FDA, which oversees 80 per cent of all food facilities in the country, ceased all inspections when the shutdown began on Dec. 22. On Jan. 15, however, the federal agency announced they would resume some of their inspections at high-risk manufacturing and processing plants.

Charlebois said Canada annually imports more than \$16 billion worth of food from the U.S. He states the U.S. supplies Canada with 94 per cent of its imported beef, 83 per cent of its imported pork and ham, and 62 per cent of its imported fresh vegetables.

Although the reduced number of inspections may seem alarming, Charlebois said this actually isn't the problem because most U.S. food producers employ their own inspectors and conduct regular third-party audits. He said the FDA doesn't conduct daily inspections and most facilities are only required to be inspected every other year.

The real concern is the lapse in regulatory oversight. This includes following up on investigations, tracking trends, and identifying possible threats to food safety. Charlebois noted the romaine lettuce recall as a perfect example. Although it took months, the government agency was eventually able to trace the source of the outbreak to a farm in California and take regulatory action. If another outbreak occurred somewhere in the U.S., Charlebois said it would be difficult to investigate it with the FDA not operating at full capacity.

Charlebois said he thinks the Canadian Food Inspection Agency (CFIA) and importers need to pay attention to the developments in the U.S. Because the U.S. and Canada are such close trading partners, the CFIA and FDA regularly share import and export data. Charlebois said the CFIA will likely have more difficulty getting information from the FDA so long as the shutdown persists.

A spokesperson for the CFIA said the agency "remains vigilant" when it comes to food safety concerns. "All food and agricultural products sold in Canada, whether domestic or imported, must comply with Canadian laws and regulations," the agency said in a statement to CTVNews.ca. The CFIA added that it hasn't received an indication of any food concerns at this time.

Charlebois said the CFIA will have better tools to source a potential outbreak from the U.S. thanks to the new regulations under the Safe Food for Canadians Act, which came into effect on Jan. 15. Under the new system, Canadian food producers, including those who import, will have to register for a license with the agency.

Source: ctvnews.ca, January 2019

https://www.ctvnews.ca/canada/canada-s-food-safety-vulnerable-during-u-s-shutdown-policy-expert-warns-1.4257456