Canadian Heart Rhythm Society
Société canadienne de rythmologie

FOR IMMEDIATE RELEASE:
Monitoring Implanted Cardiac Devices for Patient Safety

Ratika Parkash
Laurence Sterns
François Philippon
Andrew Krahn
John Sapp

OTTAWA, December 17, 2018 - The Canadian Heart Rhythm Society is a professional organization of Canada's heart rhythm specialist physicians and allied health professionals. Many of our patients are treated with implanted heart rhythm devices like pacemakers and implanted defibrillators. The medical device industry has evolved rapidly alongside technological advances. Miniaturization of battery technology, for example, has resulted in the development of pacemakers that are as small as a simple pill, and can be placed directly inside the heart. These rapid advances are providing much needed solutions to many medical problems that have been plaguing patients and the team that cares for them. Overall, these are very welcome changes to our healthcare system and improvements in patient care.

There is, however, a risk that comes along with these advances. With increasingly complex medical devices there can also be an increased risk of malfunction. Implanted heart devices are designed to function independently, but like our bodies, are subject to wear and tear and periodic malfunction. Unforeseen manufacturing defects can occur, and unexpected problems with components can arise. All devices suffer similar performance challenges. With any complex devices, there is typically an initial failure rate, which is expected but very low. This is typically followed by a long period of predictable function, with an even lower rate of failure, and then by a predictably increased rate of failure as the devices age and approach end of battery life. Appropriately, patients and health care workers are concerned when these failure rates are sudden, or higher than unexpected.

When it becomes apparent that a particular device has an unexpectedly high rate of failure, an advisory or recall may be issued by the manufacturer, a situation for which Health Canada has a process in place. As providers of health care, our goals are to help and protect Canadians with treatments and devices that are likely to provide benefit, and unlikely to cause harm. As experts in implanted heart rhythm devices, the Canadian Heart Rhythm Society (CHRS) has had a long-standing device committee, which has been working for over a decade to provide a rapid response when an advisory about unexpected device problems is received. We analyze the available information and potential risk to patients, and providing timely advice to practitioners nation-wide. In 2004, there were a number of device advisories leading to the recall of certain batteries of implantable defibrillators because of an unexpectedly high failure rate. This led to a great deal of anxiety on the parts of both patients and physicians. Individual clinicians did not know how best to respond to this information about risk, without a clear action plan to minimize that risk. After careful research by the CHRS Device Committee, it was found that the risk of harm from the potentially faulty device was much lower than the surgical risk of replacing the devices prematurely in

every patient. Lessons learned from this experience and further research has taught us that, in many cases, careful and more intense observation is often less harmful than early replacement surgery. The CHRS developed a mechanism to address recalls and advisories when they are announced by manufacturers. Working closely with device manufacturers, Health Canada, patients and physicians, we provide a national response for CIED advisories.

In 2018, the ability of the CHRS to decide how serious an advisory or recall is, and to determine the safest course of action for our patients is limited by the information available. We take note of anecdotal observations by our members, and rely on manufacturers to identify unfavourable trends within the much larger number of devices sold world-wide. A national registry of implanted devices would allow the CHRS to maintain detailed post-marketing surveillance and provide a mechanism to not only monitor complications related to device implantation, but also to identify early signals of unexpected device failure. Algorithms could be constructed to monitor device performance and detect anomalous failure rates, and protect patients from receiving devices that are at higher risk of faulty behaviour. A registry of this type could also track outcomes after interventions or responses to an advisory, so that physicians and health care systems could react appropriately.

As medical devices are central to treatment of many diseases, advances in their design provide important improvements in care. As the power to treat medical conditions increases, we must meet our obligation to responsibly use and monitor these devices safely and appropriately for Canadians.

For more information, please contact:

Ratika Parkash MD MS FRCPC
Professor of Medicine, Division of Cardiology (Arrhythmia)
Director of Research, Division of Cardiology
QEII Health Sciences Centre
Email: Ratika.Parkash@nshealth.ca
Tel: (902) 473-4474