Formation of a national network for rapid response to device and lead advisories: The Canadian Heart Rhythm Society Device Advisory Committee

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The Canadian Heart Rhythm Society (CHRS) Device Advisory Committee was commissioned to respond to advisories regarding cardiac rhythm device and lead performance on behalf of the CHRS. In the event of an advisory, the Chair uses an e-mail network to disseminate advisory information to Committee members broadly representative of the Canadian device community. A consensus recommendation is prepared by the Committee and made available to all Canadian centres on the CHRS Web site after approval by the CHRS executive. This collaborative approach using an e-mail network has proven very efficient in providing a rapid national response to device advisories. The network is an ideal tool to collect specific data on implanted device system performance and allows for prompt reporting of clinically relevant data to front-line clinicians and patients.

Key Words: *Advisory; Implantable defibrillator; Network; Pacemaker; Recall*

Recalls and advisories of cardiac rhythm devices pose significant challenges to health care professionals involved in the care of patients with implantable devices (1,2). Traditionally, device and lead malfunction have been reported by physicians to manufacturers who include this information in their periodic product performance reports. This process is limited because it depends on physician reporting of system dysfunction. In response to the recent increased number of device advisories, the Canadian Heart Rhythm Society (CHRS) commissioned a Device Advisory Committee. The CHRS is the national association of heart rhythm specialists and allied health care professionals. The Device Advisory Committee coordinates a network of Canadian arrhythmia device physicians to facilitate device and lead surveillance, rapidly evaluate and report system

Formation d'un réseau national d'intervention rapide en cas d'avis de sécurité relatifs aux instruments et aux électrodes : Comité consultatif de la Société canadienne de rythmologie sur les instruments médicaux

On a demandé au comité consultatif sur les instruments médicaux de la Société canadienne de rythmologie (SCR) de répondre au nom de cette dernière aux avis de sécurité relatifs au rendement des instruments et des électrodes cardiaques. Dans l'éventualité où un avis de sécurité serait émis, le président utilise un réseau pour transmettre par courriel l'information contenue dans l'avis aux membres du comité qui représentent largement les utilisateurs de tels instruments au Canada. Le comité prépare alors une recommandation consensuelle et après approbation par l'exécutif, il l'achemine à tous les centres canadiens par l'entremise du site Web de la SCR. Cette approche en collaboration faisant appel à un réseau d'envois par courriel s'est révélée très efficace dans les cas où il fallait réagir rapidement et à l'échelle nationale à des avis de sécurité relatifs à des instruments. Ce réseau est un outil idéal pour recueillir des données spécifiques sur le rendement des systèmes implantés et permet la transmission rapide de rapports de données cliniquement pertinentes aux principaux intéressés, qu'il s'agisse des médecins ou des patients.

malfunction, and consistently and efficiently respond to advisories. The Committee's early experience has firmly established the benefits of a highly integrated and responsive national network.

The CHRS Device Advisory Committee was formed as a result of successful national collaboration regarding device advisories since 2005. An initially ad hoc group of Canadian investigators collaborated to collect and report a larger scale 'Canadian' perspective on the outcome of device advisories (3), and has generated several ongoing projects that address outcomes in specific device-related patient groups (4-6). This group formed the nidus for the more formal assembly of the CHRS Device Advisory Committee to allow for a national collaboration on device advisories. The Committee was commissioned primarily to create a mechanism for the development of timely and informed

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responses to advisories regarding device and lead performance on behalf of the CHRS. This includes all forms of implanted heart rhythm management systems, including pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy devices, implanted cardiac monitors and their respective leads. The process includes a mechanism to notify the Chair regarding the advisory, transmission of the information to the Committee, classification of the urgency of the advisory, preparation of a consensus recommendation in response to the advisory, CHRS Executive approval, dissemination of both advisory information and CHRS recommendations to all of its members, and communication with the media and public as needed.

RESPONSE TO ADVISORIES

The Committee considers advisories when a greater degree of intervention than increased surveillance is required. Specific decisions regarding management of patients with device advisories must be individualized, taking into account device and lead factors, patient comorbidities and patient perceptions of risk after all the technical data are communicated. When a problem of potential device malfunction is identified, Committee involvement may be requested by a treating physician, device manufacturer, the CHRS Executive, or Health Canada. The Device Advisory Committee consists of a member from each ICD implanting centre and a Chair selected by the CHRS executive. Committee membership includes regional representation, both adult and pediatric centres, and at least one centre that provides follow-up but does not implant devices. The Chair's term is three years, renewable once and succeeded by the Deputy Chair. The Committee's Working Group is composed of the Chair, a Deputy Chair, the President of the CHRS, an alternate within the Chair's own institution and a member-at-large. The Committee promotes collaboration and research among its members and all CHRS members in the field of device and lead advisories, but does not have any official role with respect to endorsement or exclusivity.

ADVISORY TERMINOLOGY AND CLASSIFICATION

The evolution of terminology in this area has led to a preference for the use of the terms 'advisory' or 'safety alert' rather than 'recall', since the term 'recall' evokes a particular and unintended response from health care workers, patients and the public. The use of the term 'recall' has led to a misunderstanding of the intention in this specific context because the majority of devices in these circumstances are not actually 'recalled' (ie, replaced). The CHRS Device Advisory Committee uses the term 'advisory' because 'safety alert' implies that all such advisories influence patient safety, which is not necessarily the case. Presently, Health Canada and device manufacturers are bound by law to use the term 'recall' in all official communications pertaining to device and lead performance, regardless of the recommendation with respect to surveillance or replacement (7). Thus, communications from the CHRS that target physicians or the public generally use the term 'advisory' (indeed, the name of the Committee itself reflects this), recognizing that joint communications with Health Canada and manufacturers will need to revert to the more traditional 'recall', although all stakeholders agree that there is a need to revise the legal terminology.

Advisories are divided into two classes, depending on the gravity of the consequence to the patient of the potential device malfunction. The term 'class I advisory' applies when device replacement should be considered because of the reasonable probability that the malfunction or potential malfunction could result in death or significant harm to the patient. The term 'class II advisory' applies when the advisory involves nonlife-threatening malfunctions or potential malfunctions. This classification system is consistent with the 'recall' classification of Health Canada. Device or lead replacement is considered in the event that the mechanism of malfunction is known and is potentially recurrent, if the risk of malfunction may lead to patient death or serious harm, and if the risk of replacement is equivalent to or less than the

risk of device or lead malfunction-related harm. Device or lead replacement is considered in patients who are pacemaker dependent, or who have an ICD in the context of previously documented ventricular arrhythmia or appropriate shock for ventricular arrhythmia. Device replacement may be considered when the mechanism of the malfunction is not known, but a sufficient pattern has emerged that raises concern regarding patient safety. Conservative therapy may be indicated in patients who are not pacemaker dependent, who have not received an appropriate shock or had previous ventricular arrhythmia, or whose general medical status increases the risk of surgical device replacement to an unacceptable level. In this general context, clinical decisions must be individualized after thorough discussion of the risks and benefits with the patient.

The Device Advisory Committee supports the Heart Rhythm Society's document "Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies" by Carlson et al (7), which was developed with Canadian input through CHRS participation in Coalition of Pacing and Electrophysiology (COPE) organizations regarding many of the concerns surrounding device advisories. Many of the key principles involved in device monitoring are covered in depth in a thoughtful manner in this document. The Committee endorses the strong recommendation to increase surveillance of implanted devices, including increased physician reporting of adverse events, increased physician-directed retrieval of devices after death and increased scrutiny of device malfunction by manufacturers, reported on a semiannual basis.

ADVISORY RESPONSE PROCESS

When a device advisory is released, it is directed to the attention of the Committee Chair or a Working Group member if the Chair is unavailable. Depending on the urgency and scope of the advisory, communication is via e-mail, fax or telephone. The Chair has the responsibility to classify the advisory as urgent (requiring a response within two business days), semiurgent (requiring a response within five to 10 working days) or routine (requiring a response within 20 working days). The required urgency of a response depends on both the number of potential patients affected and the actual threat to the patient (ie, premature battery depletion, abrupt failure, inappropriate ICD shocks, etc). Committee members discuss advisories by e-mail and when needed, a conference call led by the Chair is used to arrive at a consensus regarding recommendations. The Chair archives e-mails to create an electronic record of the proceedings. Recommendations are drafted and circulated by e-mail to the entire Committee and require a response within a finite period determined by the urgency of the advisory. Consensus recommendations are forwarded to the CHRS executive and made available to all implant and follow-up centres in Canada by e-mail and posted on the CHRS Web site (www.chrsonline.ca). When a large-scale change in clinical practice is recommended (such as reoperation to replace a lead or generator), recommendations are vetted by the CHRS executive and then forwarded to the membership, and made available as needed to the media and public.

It is anticipated that Committee members will have some relationship with manufacturers. This is inevitable, and reflects both a working relationship as well as expertise in the areas with manufacturer overlap. Thus, recommendations are made in consultation with manufacturers, but do not require their approval. These relationships are disclosed, recorded by the CHRS and included in any communication with the public. It should be noted, however, that the CHRS is funded entirely by membership dues and does not accept any funding from industry for its operations.

The Device Advisory Committee recognizes the need for a Canadian voice and contribution to the International COPE and the Heart Rhythm Society with respect to device and lead advisories. It is anticipated that the Committee and its chair will interface with the president of the CHRS to provide input and representation to COPE and the Heart Rhythm Society on matters regarding device and lead advisories.

ROLE OF THE CHRS DEVICE ADVISORY COMMITTEE IN A RECENT ADVISORY; PROOF OF CONCEPT

The CHRS Device Advisory Committee has already demonstrated its success in efficiently dealing with recent major advisories. For example, in response to the Medtronic Sprint Fidelis (Medtronic of Canada Ltd) ICD lead advisory in October 2007 (8), rapid e-mail discussion among the Committee members led to the dissemination of a CHRS membership statement (www.chronline.ca) within 48 h. Data from all Canadian ICD centres regarding lead performance were collected within eight weeks and fast-tracked for publication in a leading international heart rhythm journal (6). The recommendations of the Committee regarding this advisory were highly sought after by physicians, patients and hospital administrators, and were immediately and widely recognized as a key body of thought on this issue. The broad consultative and consensus-driven process underlying the recommendations provided reassurance and certainty to decision makers in an inherently subjective environment. The CHRS response to the Medtronic Sprint Fidelis advisory is testimony to the strong collaborative nature of the Device Advisory Committee, the feasibility of obtaining comprehensive performance data when physicians are motivated, and the need for a structure that can consistently and rapidly deliver responses to patients and their physicians regarding potential device malfunction.

The CHRS Device Advisory Committee has established an electronic network that forms an early response team consisting of constituents from Health Canada, device manufacturers and the Device Advisory Committee Working Group. This group is currently working toward a goal of rapid, transparent joint communications regarding advisories, and an improved surveillance and reporting system that will involve all stakeholders. The current system is in need of a better-defined mechanism for surveillance that includes an early signal detection system. The collaborative nature and efficiency of this process will hopefully serve as a global standard for optimizing the evaluation and management of heart rhythm device advisories.

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