

Canadian Heart Rhythm Society
Standing Committee on Device Advisories
Proposed Terms of Reference and General Approach to Advisories
October 2007
Submitted by Andrew Krahn (Chair)

Preamble:

Heart rhythm device advisories have been a reality as long as there have been implanted devices and performance monitoring. The recent increase in device advisories, subsequent monitoring and reporting of device performance and adverse clinical outcomes led the Canadian Heart Rhythm Society (CHRS) to form the Standing Committee on Device Advisories. An ad hoc group of investigators began a collaboration to collect and report a larger scale “Canadian” perspective on the outcome of device advisories. This began at the annual general meeting of the Canadian Heart Rhythm Society in October of 2005, with presentation and publication of results in 2006. Subsequently, this group has generated several ongoing projects that address outcomes in specific device related patient groups. This group has thus formed a template for a National collaboration on device advisories, and the constituents of the Standing Committee on Device Advisories (Appendix 1).

Introduction:

The Standing Committee on device advisories has been commissioned to create a mechanism for responding to advisories regarding device and lead performance on behalf of the Canadian Heart Rhythm Society (CHRS). This process will include a mechanism to notify the Chair or his/her delegate regarding the advisory, distribution of the information to committee members, classification of the urgency and scope of the advisory, creation of a consensus recommendation in response to the advisory, dissemination of both advisory information and CHRS recommendations to CHRS members, and communication with the public and the media when appropriate. Recommendations with a broad effect or associated with media coverage will be vetted with the CHRS executive. It is anticipated that the majority of advisories affecting a small number of patients will be dealt with at a local level between manufacturer and individual implant and/or follow-up centers without involvement of the committee.

Advisories will be considered by the Committee if there is consideration of a greater degree of intervention than simple increased surveillance with more frequent follow-up based on Manufacturer communication to individual implant and follow-up centers. Thus a request for Committee involvement may come from an implant and/or follow-up Physician, the Manufacturer, a Committee member as well as the CHRS Executive, or Health Canada. The Committee and its Chair is expected to maintain an active, transparent relationship with Health Canada and Device Manufacturers to strive towards a unified approach to advisories with information sharing, a consistent use of language, and a “sounding board” for responses and recommendations during their development.

Terms of Reference:

1. The Standing Committee on device advisories will consist of a Chair selected by the CHRS executive, and 8-12 members. Committee membership should include regional representation as well as large and small volume centers, a Pediatric center and at least one center that provides follow-up that does not implant devices (Appendix 1). The Chair's term should be three years, renewable once. The subsequent Chair should be identified in the last year of the Chair's term, ideally from the Committee membership.
2. Advisories will be directed to the Chair for consideration. In the event that the Chair is unavailable, the Chair will designate an alternate within his or her own institution, as well as an associate Chair to act in the role of Chair in his or her absence. Communication will be in the form of e mail, fax or telephone depending on the urgency and scope of the advisory.
3. After review of the advisory details, the Chair will classify the advisory as Urgent requiring response within 2 business days, semi-urgent requiring response with 5-10 working days, and routine requiring response within 20 working days (see Appendix 2). This classification will be based on the nature of the threat to the patient (ie abrupt failure, more frequent monitoring, premature battery depletion etc) and the number of patients and centers affected.
4. Advisories will be reviewed by committee members by e mail discussion lead by the Chair, with a conference call among available members if consensus on response is not forthcoming from preliminary e mail discussion.
5. Recommendations will be drafted and circulated to the entire committee with a finite period to respond depending on urgency, with final recommendations forwarded to the CHRS executive, and made available to all implant and follow-up centers in Canada by e mail. Recommendations will also be posted on the CHRS website.
6. When an advisory results in the recommendation for a large scale change in clinical practice (such as frequent device or lead replacement), it is anticipated that recommendations will be vetted by the CHRS executive and forwarded to the membership, and made available to the public and the media when appropriate. Media communication will take place in close collaboration between the Chair and the CHRS President.
7. The Committee will promote collaboration and research amongst its members and all CHRS members in the field of device and lead advisories, but will not have any official role with respect to endorsement or exclusivity.

General Approach to an Advisory

1. The term “Class I advisory” will apply when device replacement should be considered because of the reasonable probability that the malfunction could result in death or significant harm to the patient. The term “Class II advisory” will apply when the advisory involves non-life threatening malfunctions or potential malfunctions.
2. Device replacement will be considered in the event that the mechanism of malfunction is known and is potentially recurrent, risk of malfunction may lead to patient death or serious harm, and the risk of replacement is equivalent or less than the risk of device malfunction leading to patient harm. Device replacement may be considered in patients who are pacemaker dependent, or have a defibrillator in the context of previous 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.
3. 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.

These definitions are consistent with the Heart Rhythm Society’s document entitled: “Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines” (Heart Rhythm 2006;3(10):1250-1273). A summary Table of the definitions of device performance is provided in Appendix 2.

Classification of Device / Lead Advisories

1. **Urgent:** risk of abrupt device/lead/system failure that may be life threatening without means to detect risk of failure during routine follow-up. This classification will result in a preliminary response based on available data within 2 business days. This will presumably stem from Manufacturer notification of Physicians of the advisory, and may result in urgent notification of patients. An example would be abrupt loss of pacing function, or failed defibrillation.
2. **Semi Urgent:** risk of abrupt or rapid device/lead/system failure that may be life threatening with means to detect risk of failure during routine or increased follow-up, be it remote or in a device follow-up clinic setting. This classification will result in a response based on available data within 5 business days. An example would be abrupt loss of defibrillation function in patients with impedance or battery parameters within a certain measurable range, mandating rapid assessment and closer follow-up.

- 3. Elective:** risk of device/lead/system malfunction that is not life threatening, with or without means to detect risk of malfunction during routine follow-up. The majority of these advisories would not be expected to require a specific response from the committee or CHRS, but under certain circumstances (example, highly prevalent system component in question) the Committee may choose to or be asked to generate a response. An example would be premature battery depletion that can be detected during follow-up or increased risk of lead fracture detectable with impedance monitoring. This will be dependent on the number of patients and centers affected to some degree.

Additional Considerations

- 1.** 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. These relationships should be disclosed, recorded by the CHRS, and disclosed in any communication with the public.
- 2.** The evolution of terminology has led to the use of the term advisory or safety alert and not recall. The committee acknowledges that recall evokes a certain response from health care workers, patients and the public. The concept of a recall is not intended, since the majority of devices in the circumstances are not “recalled” or replaced. The CHRS Standing Committee will utilize the term advisory, since safety alert implies that all such advisories influence patient safety, which may not necessarily be the case. **Health Canada and Device manufacturers are bound by law to use the term “recall” in all official communications surrounding device and lead performance, regardless of the recommendation with respect to surveillance or replacement. The Canadian Heart Rhythm Society endorses the Heart Rhythm Society’s recommendation to adopt the term “advisory” in place of the term recall. Thus communications from CHRS that target physicians or the public will generally use the term advisory, recognizing that joint communications with Health Canada and manufacturers will comply with their constraints in terminology.**
- 3.** The Special Committee on Device Advisories is expected to review the performance reports of the major manufactures that are made available every 3 months. Although it is anticipated that these reports are provided to all physicians involved in the care of patients with implanted devices, the Standing Committee is expected to perform a more in depth analysis of the details of the performance report, and consider a response as outlined above in the event that either the manufacturer or a physician from the committee raises concern that product performance constitutes consideration of an advisory.

4. The Standing Committee on Device Advisories supports the Heart Rhythm Society's document "Recommendations for the Heart Rhythm Society Task Force on Device Performance Policies" by Carlson et al (Heart Rhythm 2006;3(10):1250-1273). This is a comprehensive and thoughtful document regarding many of the concerns surrounding device advisories. Although the scope of it is focused on many of the aspects specific to the United States' system of monitoring and regulatory issues, many of the key principles involved in device monitoring are covered in depth in a thoughtful manner in this document. The Special 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 and reporting of device malfunction by manufactures reported on a semi annual basis.
5. The Heart Rhythm Society task force recommends creation of task forces specific to individual device types (ICD, pacemaker etc) because of the magnitude and scope of the problem in the United States. This is not felt to be a realistic goal within the Canadian system. In response, it is important that the committee have representatives with expertise in each of these areas that can act as a resource to the committee at large to address issues specific to particular types of devices.
6. The Standing Committee recognizes the need for a Canadian voice and contribution at the International Coalition of Pacing and Electrophysiology (COPE) with respect to device advisories. It is anticipated that the committee and its chair will interface with the president of the Canadian Heart Rhythm Society to provide input or representation to COPE on matters regarding device advisories.
7. The Specials Committee on Advisories acts on behalf of the CHRS membership under the direction of the CHRS Executive. As such, medicolegal indemnity flows from the role of the CHRS at large and the CHRS Executive.

Appendix 1 - Membership

Andrew Krahn – London (Chair)

Laurence Sterns – Victoria

Stanley Tung – Vancouver

Derek Exner – Calgary

Doug Cameron – Toronto

Elizabeth Stephenson – Toronto (Pediatric representative)

Jeff Healey – Hamilton

Jennifer Fraser – Peterborough (AHP representative)

Chris Simpson – Kingston

David Birnie – Ottawa

Bernard Thibault – Montreal

Jean Champagne – Quebec City

Ratika Prakash – Halifax

Mike Turabian – Brandon (Follow-up only center)

Appendix 2

Table 1 Definitions of Device Performance (adapted from Heart Rhythm 2006;3(10):1250-1273)

Definitions

1. **Device Malfunction:** Failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed (FDA Regulations 803.3(n)). Whenever possible, device malfunction should be confirmed by laboratory analysis.

A. **Device Malfunction with Compromised Therapy:** A device (pulse generator or lead) that has malfunctioned in a manner that compromises pacing or defibrillation therapy (including complete loss or partial degradation). Some examples include: sudden loss of battery voltage, accelerated current drain such that low battery voltage is not detected before loss of therapy, and sudden malfunction resulting in non-delivery of defibrillation therapy.

B. **Malfunction without Compromised Therapy:** A device that has malfunctioned in a manner that does not compromise pacing or defibrillation therapy. Some examples include: error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes battery to lose power prematurely but in a time frame that is detectable during normal follow-up before normal function is lost, and mechanical problems with connector header that do not affect therapy.

C. **Induced Malfunction:** A malfunction caused by external factors (e.g., therapeutic radiation, excessive physical damage, etc.) including, but not limited to, hazards that are listed in product labeling. Damage to a pulse generator caused by a lead malfunction is considered to be a lead rather than a pulse generator malfunction.

D. **Normal Battery Depletion occurs when:**

1. a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50th percentile) predicted longevity at default (labeled) settings, or
2. a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using the longevity calculation tool available at the time of production introduction, calculated using the device's actual settings.

Mechanisms of Malfunction

Device Malfunction Due to a Non-Repetitive Mechanism

Often called random component malfunction, statistically independent, usually rare, and non-systematic event. Examples include, but are not limited to:

1. Non-battery pulse generator failure may be caused by:
 - a. Electronic component malfunction, including the sensor(s)
 - b. Electrical overstress* in ICDs
 - c. Housing defects resulting in loss of the hermetic seal, short-circuiting, or connector malfunction
 - d. Software abnormalities
 - e. Connector malfunction due to inability to position the set screw
2. Battery failure may be caused by:
 - a. Premature depletion due to
 - 1) defects in battery manufacture or design, or
 - 2) an electromechanical defect not associated with battery depletion
3. Lead failure caused by:
 - f. Disrupted or degraded insulation
 - g. Conductor fracture or crush
 - h. Electrode corrosion or metal migration
 - i. Terminal pin defect or connector mismatch
4. Electromagnetic Interference (EMI): EMI may cause device malfunction in susceptible models.
 - j. Improperly grounded electric appliances
 - k. Radiation
 - l. Electrocautery
 - m. External defibrillation
 - n. MRI

Clinical Complications Affecting Device Performance

Examples include, but are not limited to:

1. Procedure-related
 - a. Lead displacement, including malposition and perforation
 - b. Phrenic nerve or extracardiac muscle (including diaphragmatic) stimulation
 - c. Pericardial effusion
 - d. Pocket complications, including erosion, migration, and infection
 - e. Tricuspid valve regurgitation
 - f. Other
2. Physiologic
 - a. Exit block
 - b. High defibrillation threshold
 - c. Undersensing
 - d. Post-procedural atrial fibrillation
 - e. Oversensing cardiac or extracardiac electrical activity

*Electrical overstress: a term used to describe the damage to electrical components caused by high voltages or currents that develop and arc within the pulse generator