REMOTE MONITORING
OF
IMPLANTABLE CARDIAC DEVICES

NP Forum  April 8, 2016

Kathy Paradon, RN, CNE
Cardiac Device Clinic
CK Hui Heart Centre
Types of Devices

- Pacemakers
  - Bradyarrhythmias

- Implantable Cardioverter Defibrillators
  - Tachyarrhythmias – VT, VF

- Cardiac Resynchronization Therapy (CRT)
  - Pacemakers
  - Defibrillators

- Cardiac Monitors
  - Syncopy
  - Palpitations
Evolution of Cardiac Implantable Devices

- Pacing since 1958
- Implantable Cardioverter Defibrillator 1988
- Cardiac Resynchronization Therapy 2000

Increasing complexity of device therapies and diagnostic data collection

Medtronic Implantable Defibrillators (1989-2000)

© Copyright Medtronic, Inc.
2007 Implants and Follow-up visits

North America Implants
Europe Implants
North America F/U
Europe F/U

Pacemaker
ICD
CRT

©2008 Heart Rhythm Society and European Heart Rhythm Association
Expert Consensus on Monitoring of CIEDs, Heart Rhythm, June 2008
CK Hui Implants and FU

The chart shows the number of PM implants, ICD implants, PM follow-up, and ICD follow-up from 2009 to 2015. The data is color-coded by year:
- 2009: Light blue
- 2010: Light green
- 2011: Blue
- 2012: Dark blue
- 2013: Grey
- 2014: White
- 2015: Light grey

The y-axis represents the number of implants or follow-ups, ranging from 0 to 3000. The x-axis represents the years from 2009 to 2015, grouped into categories PM implants, ICD implants, PM f/u, and ICD f/u.
Cardiac Device Patient Referral

Map of Canada showing provinces and territories, with major cities labeled.
Goals of Cardiac Device Monitoring

- **Patient Related**
  - Optimize pt’s QOL
  - Optimize device functions to meet pt’s clinical needs
  - ID pt’s at risk related device safety notices/advisories
  - Triage non-device related health problems

- **Cardiac Device Management**
  - Assess and document appropriate device function
  - ID and correct abnormal device behaviour
  - Maximize device longevity
  - ID devices nearing EOL, impending lead failure, and organize device replacement
Goals of Cardiac Device Monitoring

- **Disease Management**
  - Document arrhythmias, correlate with pt symptoms, determine appropriate device functions in response to arrhythmias
    - Atrial fibrillation, VT
  - Document diagnostic information relating to pt’s condition
    - HR histograms, pt activity, optivol, sleep apnea
  - Monitor response to therapy

- **Communication**
  - Maintain patient database
  - Communicate to patient and healthcare providers
    - Cardiac device and disease related information
  - Provide technical expertise
    - Colleagues, patients and community
Traditional Follow-up

- Treatment of patients with CIEDs requires ongoing f/u after device implantation

- Device Follow-up Clinic
  - Hospital based or physician office
    - Designated space and equipment for CIED assessment and management
  - Specially trained physicians and staff
  - Policies and procedures for Cardiac Device management

- Type of visit
  - Face to Face in-clinic visits
  - Trans-Telephonic Monitoring (1970’s)
In-clinic Visit
Trans-Telephonic Monitoring

- Limited to pacemaker follow-up
- Assessment of paced and non-paced rhythm and mode
- Magnet and non-magnet pacing rates and modes
- Provides a brief snapshot of the cardiac rhythm and may not detect intermittent problems
- Used if patient condition does not permit in-clinic f/u but should not be the sole means of pacemaker f/u
- Can be useful for frequent f/u of pacemakers nearing battery replacement
TTM Recording
Follow-up Frequency

- **Acute (PM, ICD, CRT)**
  - 1 month and 3 months post implant – in clinic
- **Maintenance**
  - Every 6-12 months
- **Intensified f/u**
  - Every 1-3 months
    - Near device EOL to device replacement
    - Device advisory/safety alerts
- **Patient Related**
  - Stability of rhythm and symptoms
  - Changes in medical therapies
  - Stability of thresholds
- **Device Related**
  - Type of device
  - Overall historical performance of the device
  - Age of the device
  - Assessment of device therapies and diagnostic data
- **Disease Related**
  - Frequency and severity of symptoms
  - Changes in cardiovascular therapy
Remote Monitoring

- **Technology first introduced in 1990s**
  - Wand-based RF to transfer data
  - 2001 wireless RF transmission of data

- **Remote interrogation**
  - Scheduled transmission of data
  - Same info obtained during in-clinic visits

- **Remote monitoring**
  - Automated transmission of data based on specified alerts related to device function and clinical events
Remote Monitoring Devices
Remote Monitoring
Innovative Use of RM

Medtronic Carelink Express

- Can be used in ER or OR setting or hospitals without a device clinic (kiosk)
- Not matched to an individual device
- Data transmitted and can be reviewed by device clinic staff/physician
Benefits of Remote Monitoring

- **Patient safety**
  - Earlier detection of arrhythmias or clinical events
    - Atrial fib, VT
    - Worsening Heart failure (HFC)
  - Enhanced device monitoring
    - Early detection of device/lead malfunctions
    - Reduction of inappropriate shocks
    - Device advisory/recall

- **Improved clinic efficiency**
  - Less time needed for interrogation/follow-up
  - Increased capacity

- **Patient convenience/satisfaction**
  - Less travel/parking expenses
  - Less missed work time
  - Easy to use

- **May improve compliance for follow-up**
Disadvantages of RM

- No ability to testing capture/sensing
  - Use of device automatic functions can provide information about changes to capture and sensing
- No ability, at present, to program or adjust device settings
  - Patient needs to come to clinic in-person for any device adjustments
Implementation of RM

- Privacy of information-provincial approval for AHS
  - PIA for each RM/CIED manufacturer
  - Device encrypted data maintained in servers outside of Canada
  - Secure Website – restricted access username/password
- IT to set up link for data transfer into Device Clinic databases
- Device clinic guidelines for follow-up, data management
- Staff training
- Patient education and enrollment
  - Determine eligibility for remote monitoring
    - Access to landline, internet, or cell phone reception
    - Patient /family or caregiver able to understand instructions
  - Patient consent – data storage
  - Patient contract/agreement for use of remote monitor
  - Demonstration of the remote monitor
  - Enroll patient on website
  - Order remote monitor or assign from clinic
- Patient sets up monitor at home
  - Begin transmission process
Carelink Website
### Transmissions/Alerts

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Received</th>
<th>Alerts</th>
<th>Event Summary</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>6-Apr-2016 2:14 AM</td>
<td></td>
<td>(1 Shock), Wireless Alert, Patient Alert, 1 Shocks Delivered for an Episode, AT/AF Daily Burden &gt; Threshold, Possible Fluid Accumulation, Low Patient Activity, 1 VT/VF, 1 VT-NS, 4 months in AT/AF since Last Session</td>
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<tr>
<td></td>
<td>6-Apr-2016 2:15 AM</td>
<td></td>
<td>Recommended Replacement Time, Wireless Alert, Patient Alert, Possible Fluid Accumulation, V. Pacing &gt; 90%, 3360 V. Sensing Episodes</td>
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<tr>
<td></td>
<td>5-Apr-2016 6:16 PM</td>
<td></td>
<td>Patient Alert, AT/AF Daily Burden &gt; Threshold, Possible Fluid Accumulation, Law Patient Activity, 19 V. Sensing Episodes, 46 days in AT/AF since Last Session</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Status</th>
<th>Battery</th>
<th>Device</th>
<th>Next Send</th>
<th>Next In Clinic Visit</th>
<th>Research Study</th>
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<tbody>
<tr>
<td>Viewed</td>
<td>2.8 V</td>
<td>Protecta™</td>
<td>12-Apr-2016</td>
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<td></td>
<td>2.8 V</td>
<td>Consulta™</td>
<td>26-May-2016</td>
<td>Apr 27, 2016</td>
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<td>2.8 V</td>
<td>Viva™ XT</td>
<td>Net Scheduled</td>
<td>06/05/2016</td>
<td></td>
</tr>
</tbody>
</table>
Roles of the Team Members

◆ Patient
  ● Use the monitor as instructed (contract/agreement)
    ◆ Not for replacement of emergency care
    ◆ Transmit only when instructed
      ● Scheduled or patient initiated transmissions
  ● Notify clinic of address changes/travel

◆ Clinic staff
  ● Dedicated personnel for timely review/reporting of transmission data
  ● Timely communication with patient and relevant healthcare providers regarding transmission data and follow-up plan

◆ Physician
  ● Review and sign-off of documentation regarding transmission data.
Roles of the Team Members

- **Device Manufacturers**
  - Development of RM technology
  - Informing clinic staff of RM disruptions/changes
  - Informing clinic staff of alerts/advisories/recalls
  - Training of clinic staff in the use of RM
  - Maintenance of secure and encrypted data servers
Society Position Statement

Canadian Cardiovascular Society/Canadian Heart Rhythm Society Joint Position Statement on the Use of Remote Monitoring for Cardiovascular Implantable Electronic Device Follow-up

Primary Writing Panel: Raymond Yee, MD, (Chair), Atul Verma, MD, Marianne Beardsall, RN, Jennifer Fraser, RN, Francois Philippon, MD, and Derek V. Exner, MD

aLondon Health Sciences Centre-University Hospital, London, Ontario, Canada
bSouthlake Regional Health Center, Newmarket, Ontario, Canada
cKawartha Cardiology Clinic, Peterborough, Ontario, Canada
dQuébec Heart Institute, Ste-Foy, Québec, Canada
eFoothills Hospital, Calgary, Alberta, Canada
New standard of care for Cardiac Device patients

Adjunct to in-clinic follow-up
- Alternating 1:1 RM with in-clinic f/u
- Intensified follow-up for aging devices/alerts/advisories

Specialty clinics – Heart Function Clinic
- Access to device diagnostic data for HF management and monitoring of medical therapy
What’s Next?

- Remote Programming
  - Technology already exists
  - Need to ensure patient safety
  - Research Studies underway
THANK-YOU