The Veterans Health Administration CART Program: Integration of Real-Time Data Collection into the Process of Clinical Care

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Overview

- VHA Data Resources for Disease Surveillance
  - VA Electronic Medical Record
  - Austin Information Technology Center
  - VA Office of Patient Care Services Programs

- CART: a new paradigm for cardiovascular disease surveillance

- CART-EP
VHA Data Resources for Disease Surveillance

• VHA-wide Electronic Health Record (CPRS/VistA)
  – Nationwide national VA Medical Record (since 1970s)
  – Organized/managed at the regional (VISN) level

• CPRS: rich data for clinical care
  – Text notes and reports
  – Laboratory data
  – Electronic order entry
  – Pharmacy
  – Images (ECGs, radiology, etc.)
VA Data Resources for Disease Surveillance

- Austin Information Technology Center (AITC)
  - Collects data from VHA facilities
    - Clinical
    - Administrative
  - Aggregates and processes data for multiple uses:
    - Administrative (workflow) tracking
    - Quality assessment
    - Health Services Research
  - Controls access for research
VHA Patient Care Services: Cardiovascular Diseases

- Quality monitoring and improvement
- Clinical oversight of cardiovascular services
  - John Rumsfeld, MD PhD: Acting Chief Consultant for CV Services
- National Programs
  - Pacemaker and ICD Surveillance
    - Western and Eastern Pacemaker Surveillance Programs
    - VA National ICD Surveillance Center
  - VHA Cardiovascular Assessment, Reporting, and Tracking (CART) Program
Limitations of Administrative Data

- Most parts of clinical records are not entirely *field-specific* data
  - Text notes and reports
  - Need for processing/abstraction of data
  - Time lag (sometimes years)
  - Risk of “loss in translation”
  - Lack of clinical granularity
- Lack of data standardization
  - Example: Left Ventricular Ejection Fraction
- Dependence on administrative coding
  - Problematic in a system where coding is not tied to reimbursement
Limitations of Administrative Data

Abstraction of data after the fact of care
Limitations of Administrative Data

Abstraction of data after the fact of care

is necessary because DATA COLLECTION is not INTEGRATED into the PROCESS of CLINICAL CARE
Limitations of Administrative Data

Use of administrative data for disease surveillance...
Limitations of Administrative Data

Use of administrative data for disease surveillance...

is like trying to monitor air traffic by reviewing jet fuel receipts
VA Patient Care Services Clinical Programs

- Pacemaker and ICD Surveillance Programs
- VA CART Program
VHA Pacemaker Surveillance Programs

• VHA has been a leader in remote pacemaker monitoring:
  – VHA National programs have existed for 28 years

• Program sites
  – Eastern (Washington, DC; Ross Fletcher, MD)
  – Western (San Francisco, CA; Edmund Keung, MD)

• Roles:
  – Remote follow-up of pacemaker function
  – Administrative tracking
  – Support of clinicians and voluntarily enrolled patients
• Established as a national program in 2003:
  – Based on successful Pacemaker Surveillance Programs
• Led by Edmund Keung, MD (San Francisco VAMC)
• Roles:
  – Remote monitoring of voluntarily enrolled patients with ICDs
  – *Remote* assessment and reporting of arrhythmia episodes
  – Support for patients and clinicians
  – Disease surveillance – Ongoing collaborations with FDA
  – Research – ancillary functions
  • VHA HSR&D funded studies in this cohort
VANISC and Western Pacemaker Programs

- Secure Data Servers based in San Francisco
- Staff of 13
- Patient population of >18,000 veterans
  - 5900 veterans with pacemakers
  - 12,516 veterans with ICDs
- 2009 Workload (device transmissions received):
  - 32,414 pacemaker transmissions
  - 43,118 ICD transmissions
VHA Pacemaker and ICD Surveillance: Limitations

- Enrollment is voluntary
- Linkage of remote monitoring programs to CPRS is problematic
- Lack of infrastructure to connect *remote* and *in-clinic* device follow-up
- Ascertainment of clinical outcomes is challenging
  - Quality Improvement
  - Device Performance/Surveillance
  - Health Services Research
VHA Cardiovascular Assessment, Reporting and Tracking (CART) Program

New Paradigm:
New Paradigm:

Integration of data collection into the process of care
The CART Concept

- Clinical tool that improves efficiency of care
  - Integration with CPRS
  - Efficient Report Generation
    - Faster than dictation
    - VHA-wide standardization
    - Report completion in real-time
- Integration of data collection into the *transaction* of care allows
  - *Transactional* quality management
  - Patient safety monitoring
  - Device Surveillance
  - Health Services Research
Catheterization Report

Generated by the VA Cardiac Assessment, Reporting, and Tracking (CART) system

Procedure Date: 4/15/2007
Attending: NEUSSNER, JOHN C
Operator: GARCIA, JORGE A

Procedures: Left Heart Catheterization, LV Angiography, Coronary Angiography,
Bypass Graft Angiography, Right Heart Catheterization, Aortography
Intra-Aortic Balloon Pump

Status: Elective
This was an inpatient procedure.
Type of procedure, site, and patient ID were verified with the patient.

Indications: Acute Coronary Syndromes, Valvular Heart Disease

ACCESS
Primary Arterial: Right Femoral, SF sheath, Seal closure

CATHETERS
Right coronary artery: JR 5, 5 Fr

LEFT HEART CATHETERIZATION

Pressures (mm Hg)
Aorta: 80/120, mean 100
Mild Aortic Valve Stenosis
Mild Mitral Valve Stenosis

LV-ANGIOGRAPHY
EF = 46% Abnormal - Global wall motion

CORONARY ANGIOGRAPHY

Native Vessels

Summary: 2 vessel CAD
Dominance: Right dominant

Stenosis Details

Segment | Stenosis Characteristics and Comments
---------|----------------------------------------------
Mid LAD  | 90 Calcified, Thrombus
Left PDA  | Diffusely Diseased
RCA (overall) | Luminal irregularities
Mid RCA  | 90 In-Stent Restenosis

* Highest % Stenosis Within Segment

BYPASS GRAFTS

# Graft Type | Insertion Segment | % Stenosis Location
-------------|-------------------|-------------------
1 SVG        | 1ST Diagonal      | 75 Artic/Ostial
                      | In-Stent Restenosis
CART-CL: 2004-2010
CART-CL: Progress

• Since 2005:
  – Nearly 140,000 total cardiac procedures in CART-CL
  – Nearly 3,000 providers

• FY-2010:
  – Cardiac procedures: approximately 15,000
  – PCI: approaching 8,000
CART vs. Austin: FY 2008

- N = 7972
  - ~27% of coronary angio cases ‡ PCI

- From same sites, same time frame, per Austin data, N = 4079
CART Transactional Quality Management

• Immediate email reporting of major complications
  – Chief CV Consultant; CART Leadership; CART QM Committee Chair

• Monthly Site QA Reports

• National Reports (VACO, CART-QM Committee)
  – Monthly Reports:
    • Procedure counts (including fiscal year to date)
    • Major adverse event counts (including fiscal year to date)
  – Bi-Annual Reports
    • Detailed site and ‘roll-up’ data; quality metrics

• Quarterly VISN-level Reports
  – VISN CMO’s
CART Q&M: Major Adverse Event Review

Automatic Notification

Committee Review

24-72 hours

Recommended Action

30 days

Resolution
New Clinical CART Modules

- CART-Peripheral
  - Peripheral arterial intervention
- CART-EP
  - Arrhythmia procedures
- CART-CPR
  - In-hospital cardiac arrest
- CART-Ambulatory
- Others?
CART - Direct Integration with ACC-NCDR

• In Progress:
  – CART-CL † NCDR-CathPCI

• Planned:
  – CART-EP † NCDR-ICD and NCDR-SAFARI

• Possible Future:
  – CART-Ambulatory † PINNACLE
CART-EP Tentative Goals

- Clinically-useful EP reporting tool
- Integration with ICD and pacemaker surveillance programs
  - Enhanced patient enrollment
- Transactional data collection
  - Transactional quality and management
  - Device Surveillance (Collaboration with FDA)
  - Health Services Research
CART-EP: Staged Implementation

• First Phase: Lifetime Device Tracking (basic elements)
  – Preimplantation evaluation
  – Implantation Procedure
  – In-clinic and in-hospital follow-up
  – Remote monitoring follow-up

• Later
  – Expanded/hierarchical data elements
  – Integration with NCDR-ICD v2
  – Expansion to include EPS/ablation procedures
CART-EP Timeline

- Spring, 2010:
  - Assemble CART-EP Working Group
  - First teleconferences
  - Conceptual Model and Data Elements
- Fall, 2010: Alpha Model (basic elements)
- Winter, 2011: Beta Model
- Beyond:
  - Expanded/hierarchical Model
  - NCDR Integration
  - EPS/ablation integration
### Encounter Information

- **Patient:** 123456789
- **Visit:** 1/1/1950
- **Device Data:**
  - **Procedure Date:** 5/7/2010
  - **Attending:**
  - **Operator (1):**
  - **Operator (2):**
  - **Case Number:**

#### Encounter Type
- **Status:**
- **Inpatient/Outpatient:**
- **Associated Assessment:**
  - Procedure, site, and patient ID were verified with the patient.
  - Re-assessment was performed immediately prior to conscious sedation and no change was noted.

#### Procedures Performed
- CRT-D implantation
- Left upper extremity venography
- Defibrillation testing

#### Indications
- Sinus node dysfunction
- AV block
- Prevention of sudden death
- Primary
- Secondary
- CRT
- Ventricular tachycardia
- Arrhythmia of unclear etiology
- Lead conductor fracture
- Lead insulation failure
- Pulse generator battery depletion
- Upgrade
- Device infection
- Product advisory/recall
- Device malfunction
- Other

#### Comments

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**Form 1**

**Reports** | **Pre-Procedural Assessment** | **Device Procedure** | **Follow-Up** | **Remote Monitoring**
Implantation Procedure

Pulse Generator
The pulse generator was connected to the leads. These two bleeding points were coagulated with the electrosurgical instrument. The pocket was irrigated with antibiotic solution using powered lavage, and a methodical wound examination was performed. The pulse generator was then placed into the pocket with the leads underneath the device.

RA Lead
A peel-away sheath was advanced over a (diluted) number guide wire, and the atrial lead was advanced to the heart under fluoroscopic guidance. After an acceptable lead position was obtained, the lead was secured with active-fixation in the right atrial appendage. After satisfactory measurements were obtained and adequate lead slack was ensured, the extravascular portion of the lead was secured to the underlying fascia with (number) 5 Vicryl sutures.

RV Lead
A peel-away sheath was advanced over a guide wire, and the ventricular lead was advanced to the heart under fluoroscopic guidance. After an acceptable lead position was obtained using curved and straight STYLEX, the lead was secured with active-fixation in the apical inferior right ventricular septum. After satisfactory measurements were obtained and adequate lead slack was ensured, the extravascular portion of the lead was secured to the underlying fascia with 5 Vicryl suture.

LV Lead
A 9F introducer sheath was advanced over a (diluted) number guide wire into the vein. A decapolar coronary sinus electrode catheter (Diagert CSL) catheter was advanced via a coronary sinus guiding catheter and the guiding catheter was securely sealed within the proximal coronary sinus. A balloon coronary sinus electrography catheter was then used to perform coronary sinus electrophysiology. A very large-caliber, lateral branch was present, and the branch was selected for lead placement. The left ventricular lead was then advanced over a 0.014” guide wire into the selected branch vein. The lead was advanced over the wire to the distal posterolateral LV, and counterclockwise sensing and LV capture were achieved. There was no diaphragmatic stimulation at maximum output. Under careful fluoroscopic monitoring, the 9F sheath was passed away. Then, the guiding catheter was carefully removed using the sliding tool after disengagement from the coronary sinus ostium. The LV lead remained stable throughout, and the lead function remained excellent. The extravascular portion of the left ventricular lead was secured to the underlying fascia and muscle fibers with (number) 5 Vicryl suture.

Access
Subclavian various access was obtained using the modified Seldinger technique.

DFT Testing
After confirming that the anesthesia was adequately deep, defibrillation testing was performed as described below. Therapy was programmed to VF only with detection cycle length set at 330 ms (167 bpm). VF was induced by T-shock.

<table>
<thead>
<tr>
<th>Test</th>
<th>Induced Shock</th>
<th>Energy</th>
<th>Sensitivity</th>
<th>Charge</th>
<th>Impedance</th>
<th>Result</th>
<th>Drop</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VF</td>
<td>20 J</td>
<td>1.2</td>
<td>3.5</td>
<td>52</td>
<td>NSR</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>VF</td>
<td>20 J</td>
<td>0.3</td>
<td>2.5</td>
<td>48</td>
<td>NSR</td>
<td>0</td>
</tr>
</tbody>
</table>

Other (comment)
### Device Settings

#### Vf Settings
- VF detection: 320 ms (188 bpm); 12/15, 3/12
- FVT detection: LV (VF) as low as 270 ms (222 bpm)
- VF detection: AV (VF) as low as 300 ms (166 bpm)
- FVT Therapy: Rx: Rx 35 ms at 2 A; A/V: Rx 55 ms at 0 A
- FVT Therapy: Rx1=ATP=1 A; Rx2: 80 ms; Rx3: 90 ms; Rx4: 35 ms and 2 A; A/V: Rx 55 ms at 0 A
- VT Therapy: Monitor only
- Wavelet Monitor (20% match)

#### Brady Settings
- Mode: DDD, Rate: 60-120
- AV Delay: 130/100 (pacing/sensed); rate adaptive A/V: ON
- PVARP: 100 ms; safety pacing ON; PVC response ON; Mode switch ON
- Atrial sensitivity: 0.3 mV
- Ventricular sensitivity: 30 mV
- Fk: output: 2 V, PW=40 ms; Pacing: 150 ms
- FW: output: 2 V, PW=40 ms; Pacing: 120 ms
- LV: output: 4 V, PW=40 ms; [LV up to LV ring]

#### ILR Settings

#### Comments
Summary: CART Program

- Post-hoc data ‡ *transactional* data collection
- Governance that mirrors ACC-NCDR
- Leveraging data collection for
  - Quality management
  - Workflow tracking
  - Health services research
Summary: VHA and Disease Surveillance

- VHA has wide-ranging programs and data resources for disease surveillance
- CPRS is a model electronic health record
- CART Program - *transactional* disease surveillance
Thank You
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- CHF-QUERI
  - Barry Massie, MD
  - Paul Heidenreich, MD

- IHD-QUERI
  - Stephan Fihn, MD
  - John Rumsfeld, MD PhD

- Pacemaker and ICD Remote Monitoring
  - Edmund Keung, MD

- VA Office of Patient Care Services

- CART Coordinating Center
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  - Hans Gethoffer Dr lng (Technical Director)
  - Tami Box
  - Meg Plomondon
  - Tom Maddox, MD
  - Tom Tsai, MD (CART-Peripheral)
  - Paul Varosy, MD (CART-EP)
  - P. Michael Ho, MD PhD
  - Greg Noonan
  - Alec Arney
  - Josie Nance

- VA Principal Deputy Undersecretary for Healthcare
  - Bob Jesse, MD PhD

CART
VA Cardiovascular Assessment, Reporting and Tracking System
Data Resources at Austin Information Technology Center

- VA National Patient Care Databases (NPCD)
  - Medical SAS Datasets (MedSAS)
- Decision Support System (DSS)
- Vital Status Files
- VHA Service Support Center (VSSC)
- Corporate Data Warehouse (CDW)
- Resident Assessment Instrument/Minimum Dataset (RAI-MDS)
- Real SSN