Medical Device Surveillance Using "Big Data" Methods

MDEpiNet Annual Meeting

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Joseph S. Ross, MD, MHS and Jonathan Bates, PhD
Center for Outcomes Research and Evaluation, Yale-New Haven Hospital

CORE Center for Outcomes Research and Evaluation | Yale School of Medicine

Background and Objective

- **FDA is actively strengthening national post-market surveillance system**
- **Goal is to understand potential uses, advantages of big data analytic approaches for detecting device-related safety (and effectiveness?) signals**
- **Methods will have wider implications once UDI system is adopted by routinely collected health data systems**

Project Overview

- **Development of signal detection “use case” that will be undertaken within the Yale BD2K Center**
- **Application of both traditional and “big data” analytic methods**
- **Partnered with ACC-NCDR to utilize Medicare-linked ICD registry, 2006-2010 data on implantations with follow-up data through 2011**

Why ICDs?

Advantages

- **Many manufacturers, models**
- **Highly effective therapy**
- **But not without risks: ~10% experience in-patient complications, ~ 10% per year long-term events**

Disadvantages

- **Many manufacturers, models**
- **No information on leads**
- **Only claims data for longitudinal events**

Project Research Objectives

- **Utilize big data analytic approaches for signal detection of device-related complications / outcomes after ICD therapy**
- **Compare the big data analytic approaches with traditional analytic approaches for signal detection of device-related complications / outcomes after ICD therapy**

Which ICDs?

- **Many manufacturers, models**
- **Excluded patients who received any ICD implanted fewer than 20 times**
- **Reviewed and reclassified as needed all other implanted ICDs, ensuring correct designation as single chamber vs. dual chamber vs. CRT**

Which complications / outcomes?

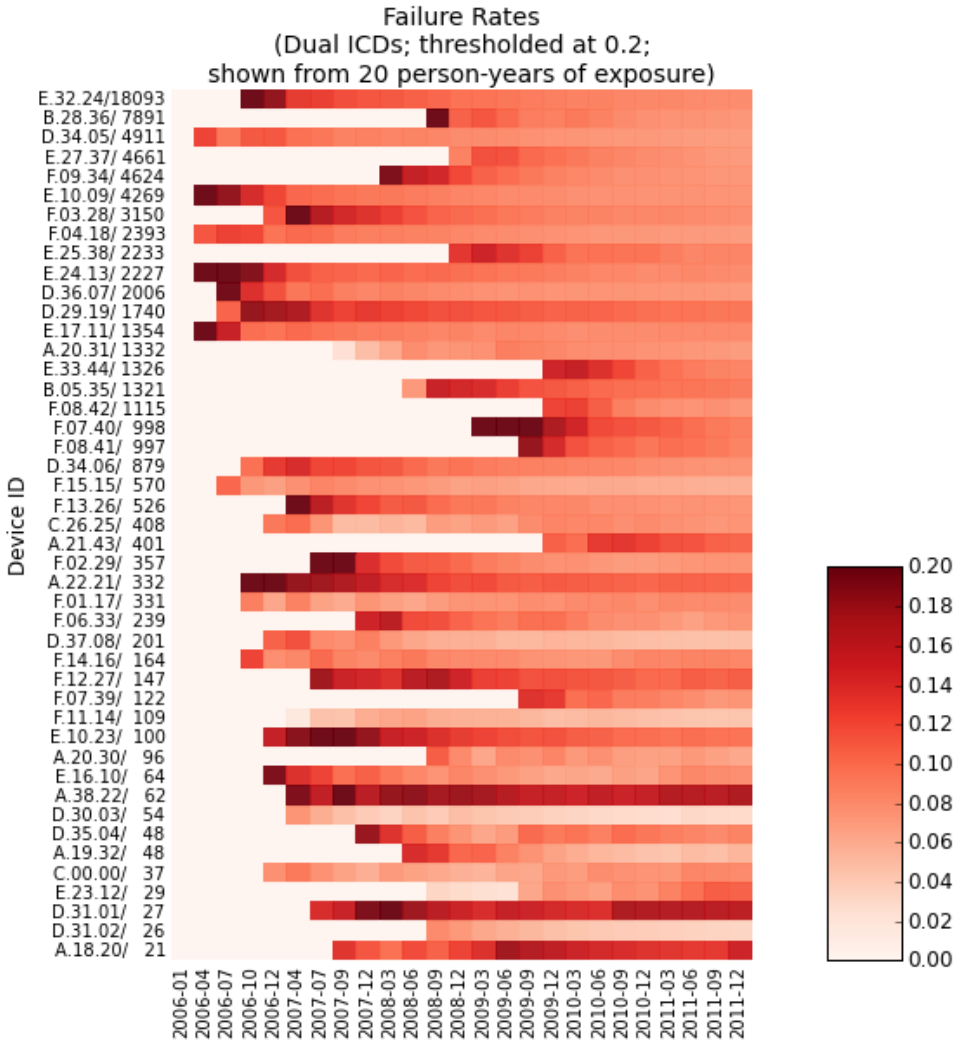
- **Death**
- **ED visit/hospitalization for an ICD-related adverse event, defined as:**
  - **Events resulting from the implantation, presence, performance, or failure of ICD therapy**
  - **But do not involve re-operation**
- **Inpatient/outpatient visit for ICD site reoperation**

Adverse Event Category	Condition Categories	Time Frame
Device Failure	CC78, 79: Respiratory Failure, CV Shock CC92, 93: Heart Arrhythmia, Other Heart Rhythm	Any
Other Device Effectiveness	CC80: Heart Failure CC81, 82: AMI, Unstable angina	Any
Infections	CC2, 6: Septicemia, Other ID CC85, 86: Heart valve dz, infections	Any
Behavioral	CC55, 58, 59: Depression, Anxiety	Any
Other Device Malfunctions	CC164	Any
Procedural Complications	CC104, 105, 106: Vascular-related	90 days
Procedural Complications	CC114: Pneumothorax-related	90 days
Procedural Complications	CC131: Acute renal failure	90 days
Procedural Complications	CC165: Other surgical related	90 days

Which Methods?

- All analyses stratified by ICD-type (single-chamber, dual-chamber, CRT)
- Will start with overall analysis to determine whether there is a signal to detect …
- Then will compare and contrast 3 methods
  - Traditional time-to-event methods, risk-adjusted for patient and procedural characteristics
  - DELTA method, prospective propensity score matching
  - Big Data methods

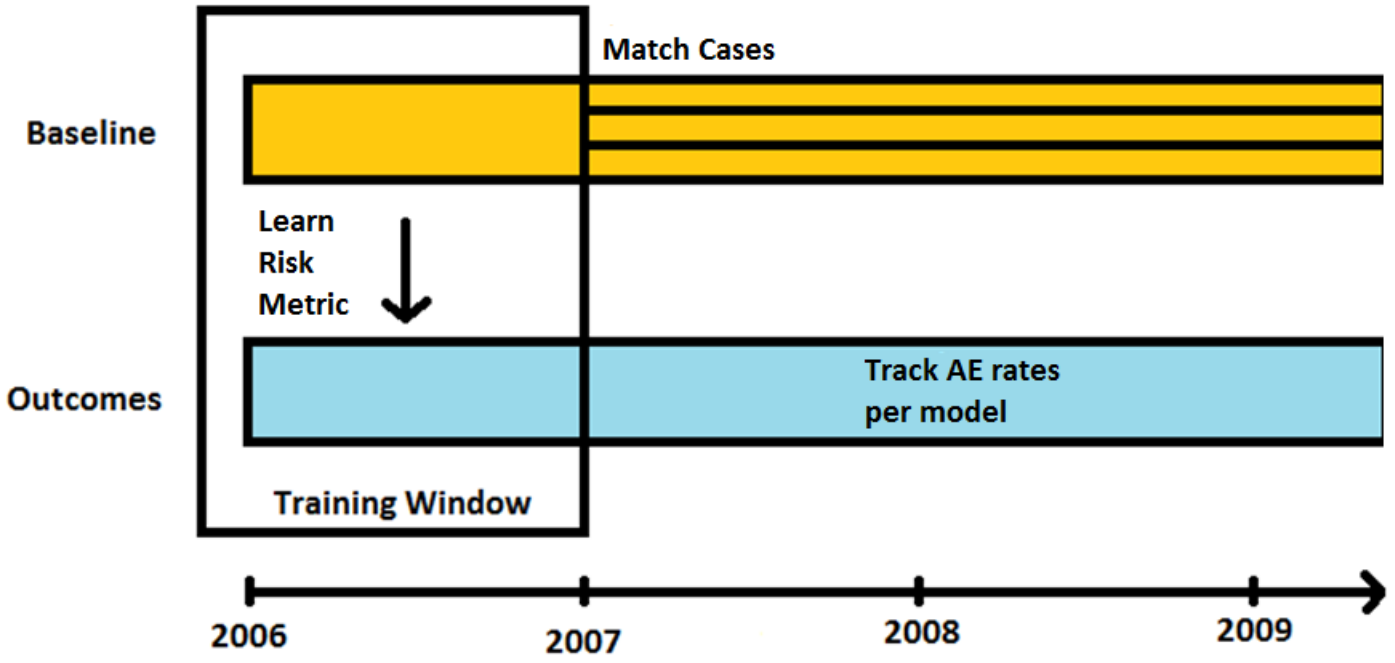
“Big Data” Approach



“Big Data” Approach

1. *Learn* a metric associated with risk between patients at baseline (implantation) using the diffusion distance between Deep Neural Network meta-features
2. Use a matching algorithm with respect to the risk metric to match cases to controls
3. Test for differences in proportions for adverse events per quarter between cases and controls

“Big Data” Approach



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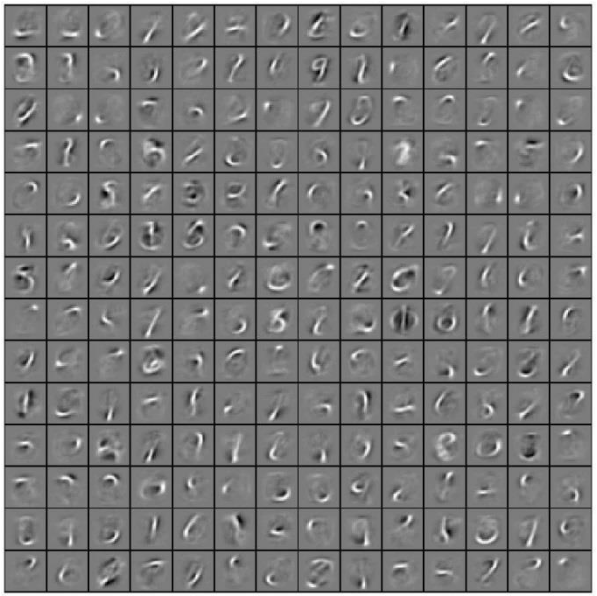

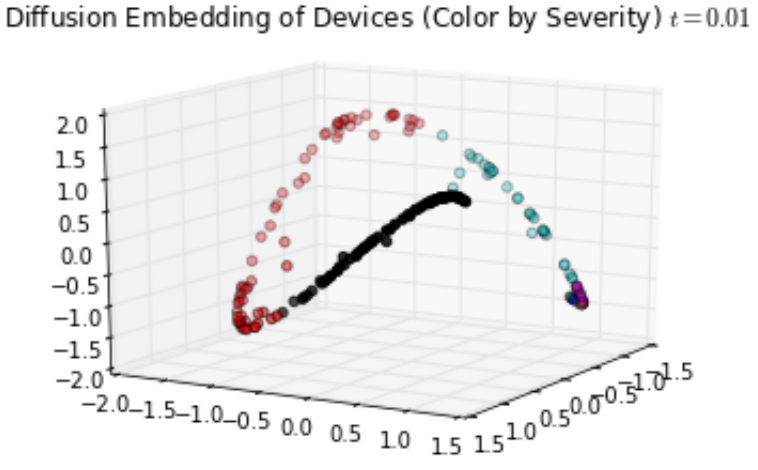

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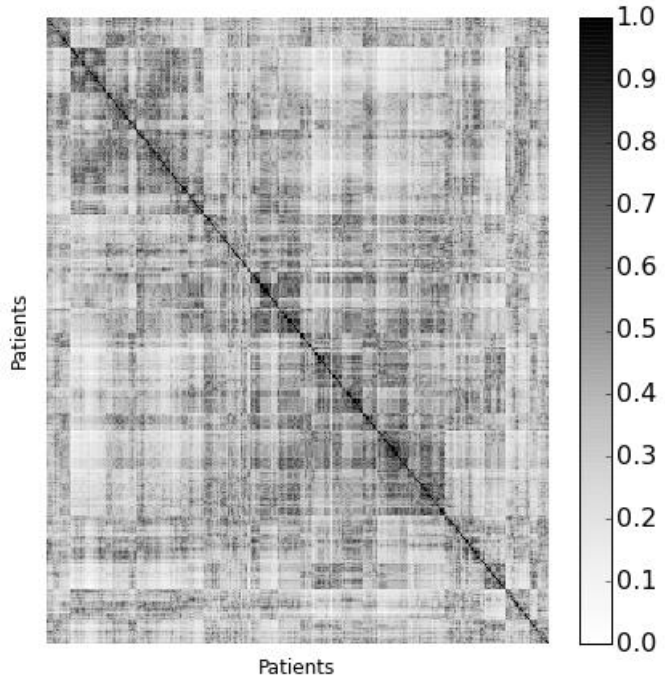

“Big Data” Approach

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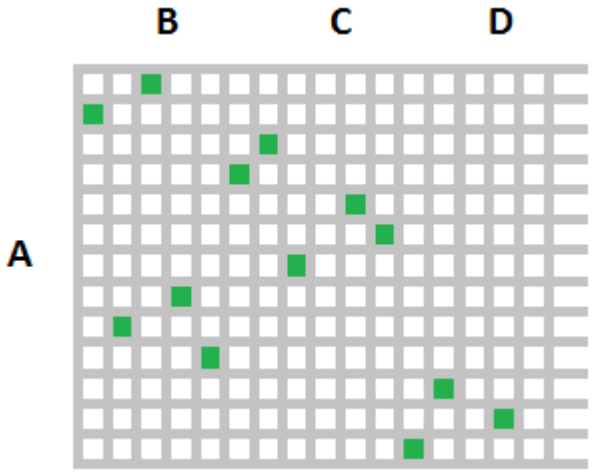

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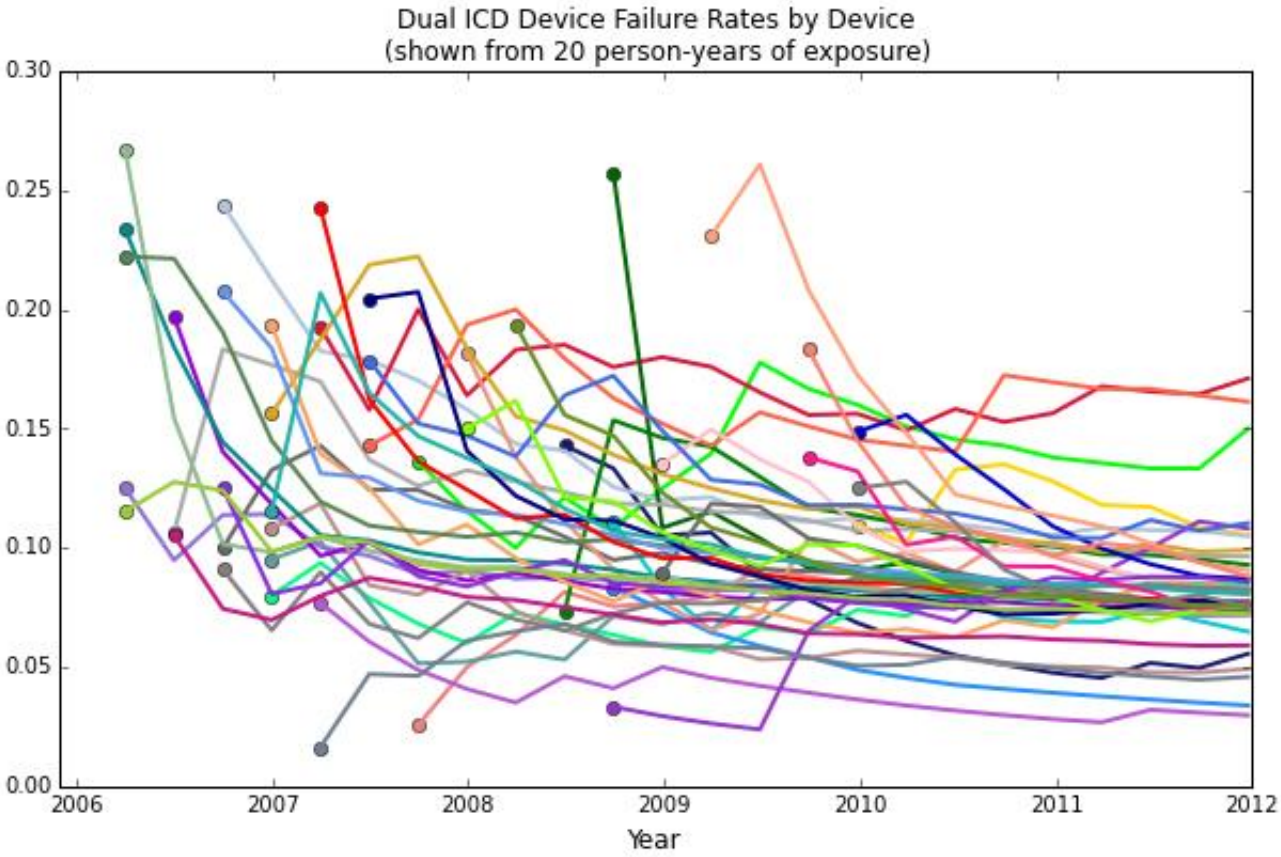
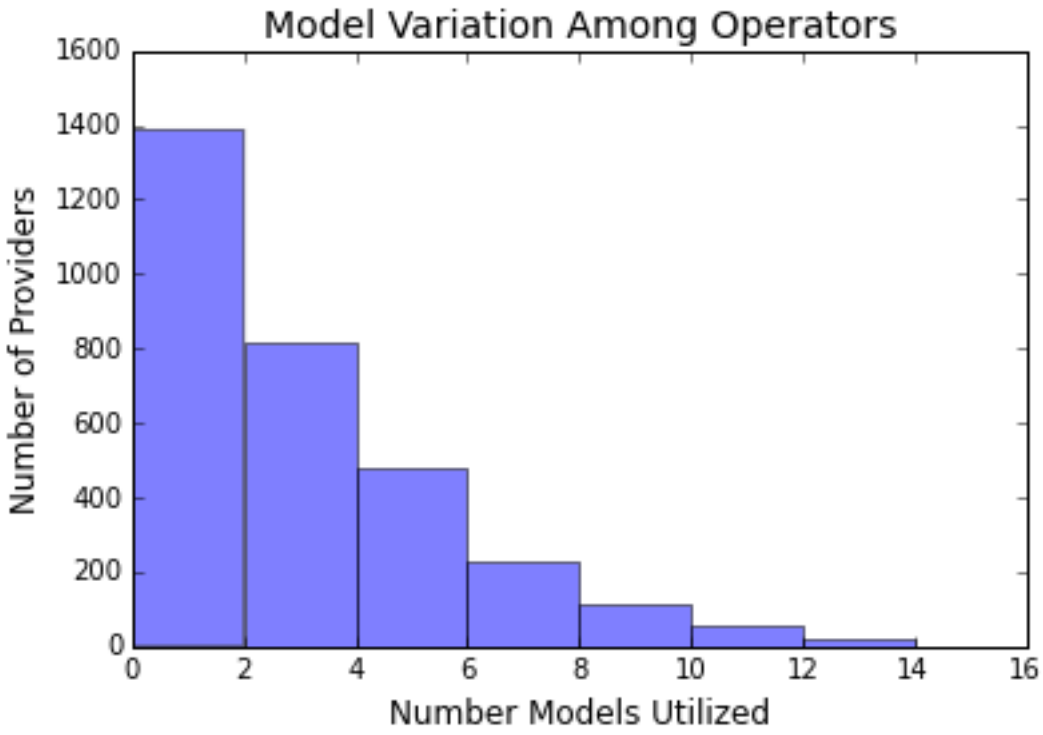

Dual ICD Device Failure Rates by Device
(shown from 20 person-years of exposure)
0.30
0.25
0.20
0.15
0.10
0.05
0.00
2006
2007
2008
2009
2010
2011
2012
Year


Model Variation Among Operators
Number of Providers
1600
1400
1200
1000
800
600
400
200
0
0
2
4
6
8
10
12
14
16
Number Models Utilized