Kaiser Permanente Cardiac Device Registry: Linking Multiple Data Sources with EHR to Assess Post Market Device Safety

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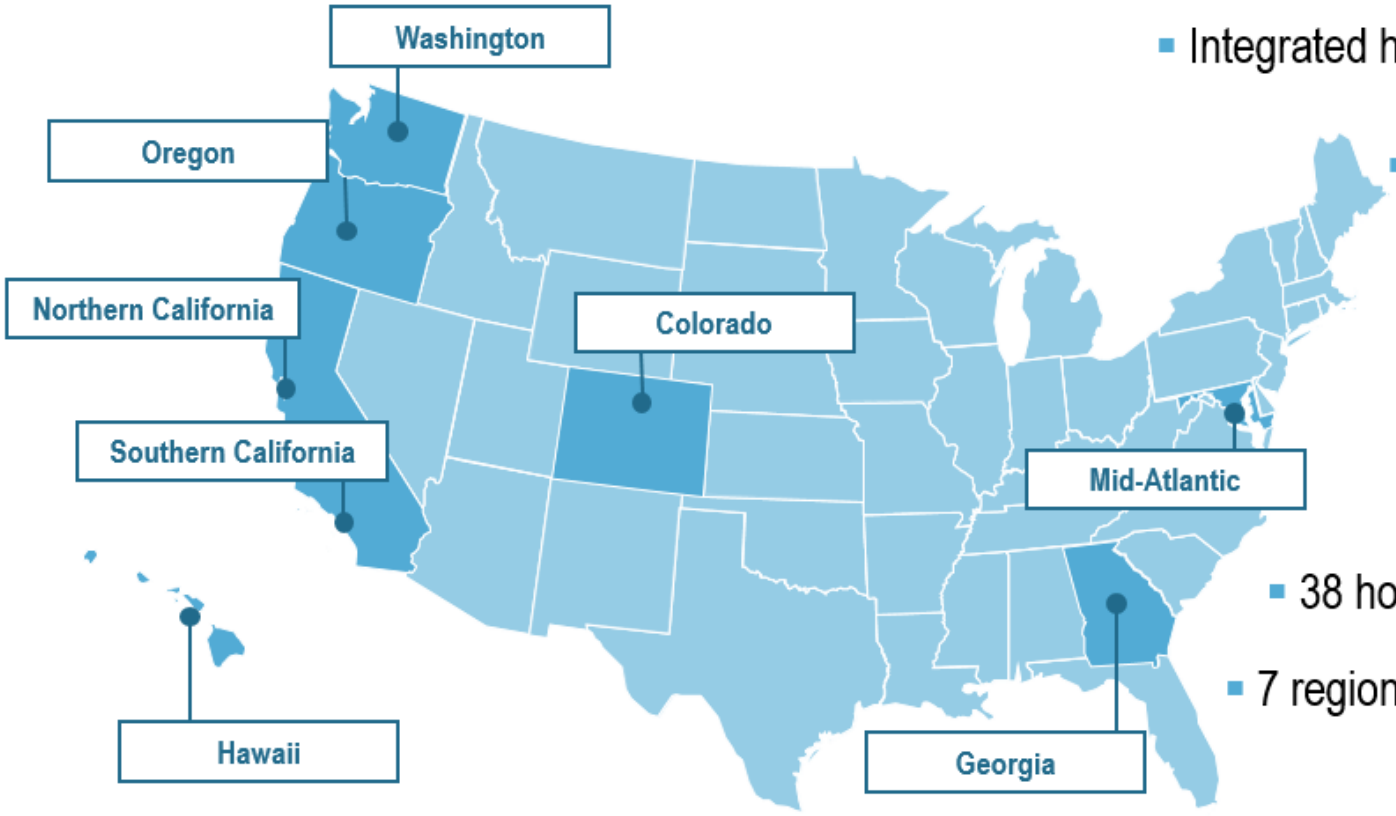
About Kaiser Permanente



- Nation's largest nonprofit health plan
- Integrated health care delivery system
- Over 10 million members
- 17,000+ physicians
- 177,000+ employees
- 600+ medical offices
- 38 hospitals and medical centers
- 7 regions serving 8 states and D.C.

Our Implant Registries

National Implant Registries Cumulative Volume > 1.67 Million Implants

Registry	Total # of Cases (YE 2014)
Total Joint Replacement	222,069
Cardiac Device	100,065
Hip Fracture	33,172
ACLR	30,526
Heart Valve	24,528
Spine	23,963
Shoulder Arthroplasty	11,496
AAA Stent	3,263

Average Annual Volume: KP Cardiac Device Registry

Device Type	# Initial	# Replacement	Combined
Pacemaker	3500	1400	4900
ICD	1600	1000	2600
Total	**5100**	**2400**	**7500**

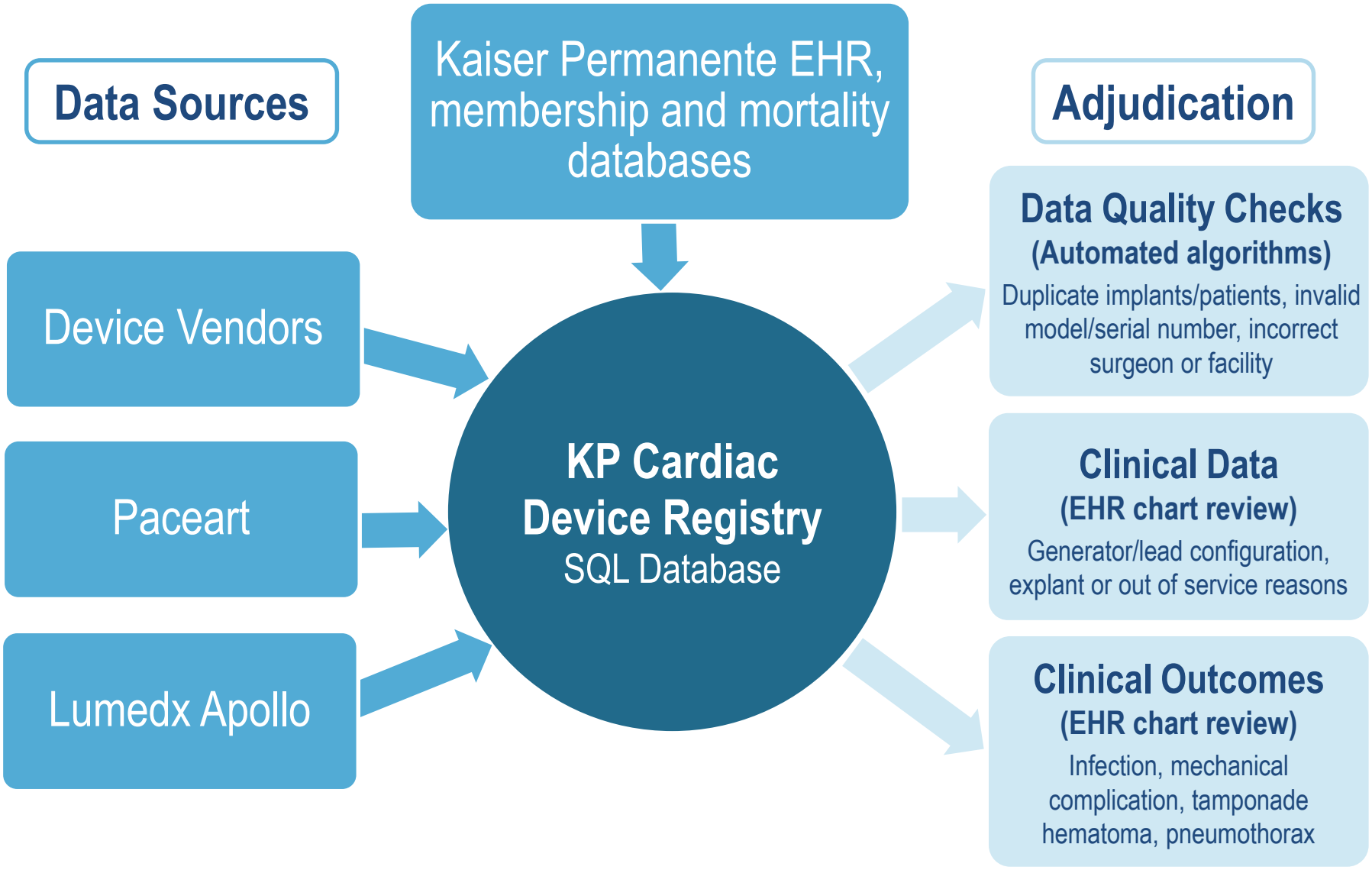
Proven Benefits of Cardiac Device Registry

- Patient safety
  - Immediate identification of patients with recalled device or lead
  - Identify patients at risk for poor outcomes
- Post market surveillance of devices
  - Monitor claims of new device features
  - Best performing or outlier devices
- Comparative effectiveness research
  - Clinical best practices for quality improvement

Data Elements in Registry

- Patient
  - MRN, patient name, DOB, gender, death date
- Implant
  - Manufacturer name,
  - Model # / serial #, type
  - Lead length
- System
  - Surgeon
  - Implanting facility, region
- Clinical Data
  - Anatomical location of implant
  - Implant, explant, or out of service dates and reasons
  - Generator and lead configuration
- Validated Outcomes
  - Infection
  - Tamponade, hematoma, pneumothorax
  - Mechanical complication of device or lead

Overview of Cardiac Device Registry



Data Source: Device Manufacturers

- Features
  - Accurate device info (model and serial #)
  - Well established tracking systems as required by FDA
  - Includes procedures performed at KP facilities
- Limitations
  - Missing data on members whose procedure occurs outside of KP
  - Vendor records purchasing facility, not implanting site
  - Does not include KP MRN so need to reconcile patient identity

Data Source: Medtronic Paceart

- Features
  - Includes KP MRN
  - Requires patient follow-up at KP to be entered into system
  - Includes implants from KP and non-KP facilities
- Limitations
  - Not all facilities on integrated Paceart data network
  - Data inconsistent among facilities
  - Relies on manual data entry
  - No direct connection to EHR currently

Data Source: Lumedx Apollo

- Features
  - Reliable data accuracy for submission to ACC-NCDR
  - Includes KP MRN
  - Captures detailed data for pre, intra and post-op
- Limitations
  - To reduce duplicative data entry for clinic staff, many facilities record only those patients with ICDs who ≥ 65 years old
  - Relies on manual data entry
  - No direct connection to EHR

EHR link to Registry Database

- Features
  - Patient identifiers: KP MRN, DOB, race, gender
  - Clinical factors: Procedure, diagnosis, co-morbidities
  - System factors: Implanting physician, facility
  - Supplemental data
    - Mortality, diabetes registry, Claims, membership status
- Limitations
  - Relies on manual data entry for implant data
  - Incomplete device info recorded due to data entry redundancy

Why multiple data sources?

- Accuracy: Verify accuracy of device data
- Completeness: Ensure complete data capture of our KP population
- Outcomes: Link to EHR is critical to evaluate longitudinal clinical outcomes

Systematic Processes of:

1) Data Cleaning (automated)

2) Clinical Data Quality (requires adjudication)

3) Clinical Outcomes (requires adjudication)

Automated Algorithms for Data Cleaning: Identifies and reconciles aggregated raw data

Automated data quality checks for inconsistencies from all sources

- Conflicting patient identifiers
- Duplicate implants
- Invalid model/serial number or device type
- Incorrect surgeon name
- Inaccurate facility name

Adjudication of Clinical Data

2500 charts reviewed annually

EHR review to resolve:

- Pulse generator and lead configuration
- Anatomical location of implant
- Explant or out of service reasons
- Same day/same implant inconsistences

Adjudication of Clinical Outcomes

800 charts reviewed annually

Validation of device and clinical complications in EHR

- Infection
- Mechanical complication
- Tamponade
- Hematoma
- Pneumothorax
- Early explants
- Lead only procedures

Strengths of KP Cardiac Device Registry

- System-wide integration across 7 regions, 10 million members
- Centralized, secure data repository with consistent methodology
- Generalizable, diverse population for analyses of risk or practice variation
- Longitudinal follow-up of implants for patients' lifetime in our system
  - Low attrition (<10%) in registered patients
- Linkage to EHR for adjudication of data quality and clinical outcomes

Conclusions

- Multiple data sources add complexity, but necessary to improve accuracy and completeness of device data
- Integration of tracking and monitoring systems into EHR is necessary for longitudinal follow-up
- Adjudication is essential for accurate and reliable data and for outcomes reporting

Thank You