Kaiser Permanente Registry Contribution to National CRNs
MDEpiNet Annual Meeting, October 1, 2015

Liz Paxton, Director, National Implant Registries
About Kaiser Permanente

- Nation’s largest nonprofit health plan
  - Integrated health care delivery system
    - 9 million members
    - 12,000+ physicians
    - 140,000+ employees
    - 430+ medical offices
    - 32 hospitals and medical centers
    - 7 regions serving 8 states and D.C.

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Kaiser Permanente Registries

- Monitor clinical outcomes
- Identify risk factors
- Identify variations in care and clinical best practices
- Identify/purchase best performing devices for our patients
- Early identification of device failures/recalls
- Comparative effectiveness research

A Learning Health Care System

Information-rich, patient focused enterprises

Evidence is continually refined as a byproduct of care delivery

Information and evidence transform interactions from reactive to proactive (benefits and harms)
### Orthopedic Registries

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Joint</td>
<td>216,000</td>
</tr>
<tr>
<td>Hip Fracture</td>
<td>28,000</td>
</tr>
<tr>
<td>ACLR</td>
<td>30,300</td>
</tr>
<tr>
<td>Spine</td>
<td>19,500</td>
</tr>
<tr>
<td>Shoulder</td>
<td>9,400</td>
</tr>
</tbody>
</table>

### Cardiac/Vascular

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICDS</td>
<td>30,900</td>
</tr>
<tr>
<td>Pacemakers</td>
<td>69,000</td>
</tr>
<tr>
<td>Leads</td>
<td>140,120</td>
</tr>
<tr>
<td>Heart Valve</td>
<td>24,500</td>
</tr>
<tr>
<td>EVAR</td>
<td>3,260</td>
</tr>
</tbody>
</table>
Method: Standardized EHR Documentation
Extracted from Electronic Health Record

**Implant Components**
- Company Name
- Catalog #
- Lot/Serial #
- Quantity

**Patient Demographics**
- Medical Record #
- DOB
- Gender
- Race

**Registry Forms**
- Electronic SmartForm/Paper
  - Procedures
  - Diagnoses
  - Surgical Characteristics
  - Fixation Types

**Implant Reference Table**
- Company Name
- Catalog #
- Description
- Name
- Attributes

**Other Data Systems**
- Claims
- Diabetes Registries
- Membership
- Mortality
- GEMS

**Registry SQL Database**

**Registry Deliverables**
- Annual Reports
- Ad-Hoc Requests
- Web-Based Reports
- Risk Calculators
- Research Projects
- Recalls/Advisories
- Personalized Surgeon Profiles
- Outlier Implants
- Risk adjusted hospital outliers
Feedback Mechanisms

**Surgeon Profile Reports**
Personal comparison of patient demographics, implants, techniques and outcomes to others in their medical center, region, and nationwide.

**Quality Reports**
Quarterly reports on post-operative complications, readmissions and mortality in an interactive dashboard summary.

**Implant Surveillance**
Incorporates validated time and risk-adjustment methods to individually review devices, and identify those with a revision ratio higher than expected.

**Newsletters and Webinars**
Dissemination of key clinical findings in quarterly webinars and routine e-news promoting discussion of current presentations and publications.

**Infection and Revision Risk Calculators**
Allow surgeons to predict a patient’s risk of SSI or Revision within one year subsequent to TKA, THA, or ACLR.

**Dynamic Registry Reports**
On-demand reports which query registry data for information on complications, infection type, and demographics by region, facility, date range, and procedure.

**Internal and External Websites**
Access our latest presented or published work, download request forms, access dynamic reports and risk calculators and view recent recalls. implantregistries.kp.org

**SmartForms**
Innovative electronic method that collects uniform data at the point of care within KP HealthConnect.
KP Registries Successes

- Longitudinal tracking of > 2 million medical devices
- Identification medical center variation and QI implementation
- Early identification of outlier devices
- Identified personalized patient risk for treatment decision making
- Influence changes in practice and improvement in outcomes
- Identification and monitoring of recalled devices
KP Strengths & Limitations

**Strengths**

- 100% capture rate of all encounters
- Long term follow-up with low attrition  
  - <8% loss to follow-up over 15 years
- Data quality  
  - Rigorous quality control  
  - Endpoints are validated through chart review  
  - Linkage to medications, labs, etc in all encounter settings

**Limitations**

- National contract for devices limit exposure to every device and manufacturer
- Success based on integrated health system infrastructure  
  - Other health care systems may not be able to replicate
Opportunities for an Orthopedic CRN

- **ICOR Success**
  - Distributed data network approach
  - Global standardized implant database
- **US total joint registries quality metrics work**
- **Interest and dedication to enhancing patient safety and quality of care**
ICOR Global Standardization Database

- Previously, each registry developed and maintained own clinical attributes reference database: No standardization

- ICOR developed global, standardized classification system of hip and knee implantable devices based on their clinical attributes and characteristics to advance the implementation of UDI and FDA postmarket surveillance
ICOR Catalog Framework: Knees

Component Identification

- Femoral Component (Unicompartmental, Trochlea, Total)
- Tibial Component (Unicompartmental, Total)
- Patella (Unicompartmental, Total)
- Baseplate (Unicompartmental, Total)
- Non-Modular (Monoblock) (Unicompartmental, Total)
- Knee Insert (Unicompartmental, Total)
Total Knee Implants: Insert

Material
- Conventional Polyethylene
- Highly-Crosslinked Polyethylene
- Vitamin E Infused Highly-Crosslinked Polyethylene

Thickness
- XXXmm x XXXmm

Size
- XXmm or S/M/L

Stability
- Cruciate Retaining
- Posterior Stabilized
- Constrained/Hinged

Mobility
- Fixed
- Rotating
- Sliding
Application of ICOR Database to Surveillance: International Consortium of Orthopaedic Registries

Risk of Revision Following Total Hip Arthroplasty: Metal-on-Conventional Polyethylene Compared with Metal-on-Highly Cross-Linked Polyethylene Bearing Surfaces
International Results from Six Registries
Elizabeth Paxton, MA, Guy Cafri, PhD, MStat, Leif Havelin, MD, PhD, Susanna Stea, BSc, Francesc Pallisó, MD, Stephen Graves, MBBS, DPhil, FRACS, FAOorthA, Daniel Hoeffel, MD, and Art Sedrakyan, MD, PhD

National and International Postmarket Research and Surveillance Implementation
Achievements of the International Consortium of Orthopaedic Registries Initiative*
Art Sedrakyan, MD, PhD, Elizabeth Paxton, MA, Stephen Graves, MBBS, DPhil, FRACS, FAOorthA, Rebecca Love, MPH, RN, and Danica Marinac-Dabic, MD, PhD

International Comparative Evaluation of Knee Replacement with Fixed or Mobile Non-Posterior-Stabilized Implants
Robert Namba, MD, Stephen Graves, MBBS, DPhil, FRACS, FAOorthA, Otto Robertsson, Med Dr, Ove Furnes, MD, PhD, Susanna Stea, BSc, Lluís Puig-Verdú, PhD, Daniel Hoeffel, MD, Guy Cafri, PhD, MStat, Elizabeth Paxton, MA, and Art Sedrakyan, MD, PhD

Effect of Femoral Head Size on Metal-on-HXLPE Hip Arthroplasty Outcome in a Combined Analysis of Six National and Regional Registries
Alex Allepuz, MD, MPH, Leif Havelin, MD, MPH, Thomas Barber, MD, Art Sedrakyan, MD, PhD, Stephen Graves, MBBS, DPhil, FRACS, FAOorthA, Barbara Bordini, BSc, Daniel Hoeffel, MD, Guy Cafri, PhD, MStat, and Elizabeth Paxton, MA
U.S. Registry Network

- US registries consensus on need for US national quality metrics
- Mini-sentinel model
  - Guiding principles and priorities
  - Distributed data network with aggregate level data
- Common data model with key quality metrics
  - Data survey of registry data elements, codes, definitions
  - Comparison of data elements, codes and definitions
## Patient demographics

<table>
<thead>
<tr>
<th></th>
<th>AJRR</th>
<th>CJRR</th>
<th>FORCE-TJR</th>
<th>HealthEast</th>
<th>KP TJRR</th>
<th>MARCQI</th>
<th>Virginia</th>
<th>Proposed Measures in Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laterality</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>Laterality</td>
</tr>
<tr>
<td>Op Date</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>Op Date</td>
</tr>
<tr>
<td>Age</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>Age</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>BMI</td>
</tr>
<tr>
<td>Gender</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>Gender</td>
</tr>
<tr>
<td>ASA Score</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>ASA Score</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>ICD-9 code, Description and POA Flag</td>
<td>ICD-9 code</td>
<td>x</td>
<td>Surgeon reported/ICD-9</td>
<td>ICD-9 Code, Description and POA Flag</td>
<td>ICD-10 Code and Description</td>
<td>Diagnosis</td>
<td></td>
</tr>
</tbody>
</table>

### Comorbidities

- Selected conditions based on ICD-9 code, e.g. diabetes, medication history, e.g. beta-blockers; SF-36; selected labs
- Selected ICD-9 codes associated with joint procedure hospitalization that may be risk factors, e.g. CAD, dialysis, MI history, immunocompromised
- Musculoskeletal pain index; patient-reported symptoms, function, activities (HOOS/KOOS, SF-36, medical conditions)
- Charlson Comorbidity Index
- Elixhauser comorbidity algorithm applied to total joint procedure hospitalization codes; KP diabetes registries
- Smoking, alcohol use, selected pre-op lab values, medication utilization, and conditions, e.g. creatinine, diabetes, based on ICD-9 codes, EHRs, patient report
- Lower Extremity Activity Scale
- Diabetes determined by presence of ICD-9 discharge diagnosis code; discuss using Charlson or Elixhauser index
# Procedure and Implant

<table>
<thead>
<tr>
<th>Procedure</th>
<th>AJRR</th>
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<th>Virginia</th>
<th>Proposed Measures in Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure ICD-9 code</td>
<td>ICD-9 Code and Description</td>
<td>ICD-9 Code</td>
<td></td>
<td>x</td>
<td>Surgeon reported; confirmed with ICD-9 codes</td>
<td>ICD-9 Code and Description</td>
<td>CPT Code and description</td>
<td>Procedure limited to ICD-9 procedure codes 81.51, 81.54, 81.53, 81.55; exclude UKA cases by CPT code or implant information</td>
</tr>
</tbody>
</table>

| Reference/Catalog Number | x | x | x | x | x | x | x | x | Implant catalog/reference numbers |
| Manufacturer | x | x | x | x | x | x | x | x | Manufacturer |
# Key Quality Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Proposed Measures in Common</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mortality</strong></td>
<td>Mortality during index procedure stay</td>
</tr>
<tr>
<td>AJRR</td>
<td>Mortality during index procedure hospital stay, or a readmission, ED visit, or clinic visit at index procedure hospital within 90 days if visit coding includes CJRR ICD-9-CM triggering codes</td>
</tr>
<tr>
<td>CJRR</td>
<td>Patient reported adverse events (ER, readmissions, dislocation, DVT/PE, infection, revision, mortality, functional improvement) at 8 w, 6 m, 12 m, and annually, validated against clinical records</td>
</tr>
<tr>
<td>FORCE-TJR</td>
<td>x</td>
</tr>
<tr>
<td>HealthEast</td>
<td>90-day mortality from EHRs and SSDI</td>
</tr>
<tr>
<td>KP TJRR</td>
<td>90-day mortality captured by abstractors from EHRs</td>
</tr>
<tr>
<td>MARCQI</td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td></td>
</tr>
<tr>
<td><strong>ED Visits</strong></td>
<td>ED Visit within 30 days</td>
</tr>
<tr>
<td>AJRR</td>
<td>ED visit at index procedure hospital within 30 days if visit coding includes CJRR ICD-9-CM triggering codes</td>
</tr>
<tr>
<td>CJRR</td>
<td>See above</td>
</tr>
<tr>
<td>FORCE-TJR</td>
<td>ED visits within 30 days of discharge</td>
</tr>
<tr>
<td>HealthEast</td>
<td>No ED visit for any reason within 30 days; if readmitted through ED case is counted under readmissions and excluded from ED visit rate</td>
</tr>
<tr>
<td>KP TJRR</td>
<td>First ER visit for any reason within 90 days. If patient is readmitted, do not record ER visit but choose readmission instead</td>
</tr>
<tr>
<td>MARCQI</td>
<td></td>
</tr>
<tr>
<td>Virginia</td>
<td></td>
</tr>
<tr>
<td><strong>Readmission</strong></td>
<td>Readmission within 30 days</td>
</tr>
<tr>
<td>AJRR</td>
<td>Readmission at index surgery hospital within 30 days if visit coding includes CJRR ICD-9-CM triggering codes</td>
</tr>
<tr>
<td>CJRR</td>
<td>See above</td>
</tr>
<tr>
<td>FORCE-TJR</td>
<td>x</td>
</tr>
<tr>
<td>HealthEast</td>
<td># of cases with &gt;=1 ED visit for any reason within 30 days</td>
</tr>
<tr>
<td>KP TJRR</td>
<td># of cases with unplanned readmission that meets CMS criteria within 30 days</td>
</tr>
<tr>
<td>MARCQI</td>
<td>Readmitted for any reason (other than another total elective joint procedure) within 90 days and billed as “inpatient”</td>
</tr>
<tr>
<td>Virginia</td>
<td></td>
</tr>
</tbody>
</table>

18
# Key Quality Metrics

<table>
<thead>
<tr>
<th></th>
<th>AJRR</th>
<th>CJRR</th>
<th>FORCE-TJR</th>
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<th>MARCQI</th>
<th>Virginia</th>
<th>Proposed Measures in Common</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DVT</strong></td>
<td>90-day DVT rate based on ICD-9 codes from readmission, ED, or clinic visit at index procedure facility</td>
<td>90-day DVT rate based on ICD-9 codes from readmission, ED, or clinic visit at index procedure facility</td>
<td>See above</td>
<td>x</td>
<td>90-day DVT based on AHRQ PSI 12 codes and chart review</td>
<td>Diagnosis, confirming imaging study, and treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PE</strong></td>
<td>90-day PE rate based on ICD-9 codes from readmission, ED, or clinic visit at index procedure facility</td>
<td>90-day PE rate based on ICD-9 codes from readmission, ED, or clinic visit at index procedure facility</td>
<td>See above</td>
<td>x</td>
<td>90-day PE based on AHRQ PSI 12 codes and chart review</td>
<td>Diagnosis and confirming imaging study</td>
<td></td>
<td>PE during hospital stay determined by ICD-9 diagnosis code</td>
</tr>
<tr>
<td><strong>Revision</strong></td>
<td>If reported</td>
<td>If at index procedure hospital</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td>Revision</td>
</tr>
</tbody>
</table>
# Proposed Common Data Elements

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>Procedural</th>
<th>Surgeon</th>
<th>Hospital</th>
<th>Implants</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Procedure</td>
<td>Surgical Approach Fixation</td>
<td>Case volume Hospital setting</td>
<td>Catalog #</td>
<td>Mortality</td>
</tr>
<tr>
<td>Gender</td>
<td>Fixation</td>
<td>Fellowship training</td>
<td></td>
<td>Name</td>
<td>Revision</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td>Case volume</td>
<td></td>
<td>Company</td>
<td>Re-operation</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td>Description</td>
<td>Re-admission</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
<td>Clinical</td>
<td>ED visits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>attributes</td>
<td>DVT/PE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(linkage to ICOR global database)</td>
<td></td>
</tr>
</tbody>
</table>
Developing a Coordinated Registry Network

- **AJRR**
  - Large volume with comprehensive implant collection

- **FORCE-TJR**
  - Patient reported outcomes

- **Kaiser Permanente**
  - Long-term follow-up and validated outcomes
Challenges

- Registries developed for different purposes using different methodologies
- Different data elements with various definitions, codes
- Loss to follow-up is a critical issue
- Long-term follow-up not yet available for most registries
- Concerns regarding data security, privacy, legal issues
Steps to Collaboration

- Create a common data model with harmonized data elements
  - Infrastructure for signal detection, comparative effectiveness research and a national post market surveillance system.

- Apply ICOR global implant database to US registries to standardize and harmonize total joint devices and their clinical attributes.

- Conduct a series of comparative effectiveness studies examining new technologies and total joint outcomes using a distributed US data network.

- Conduct confirmatory signal detection methods using existing US registry data and develop framework for a US total joint replacement registries signal detection network.
Opportunities

- **Patient safety**
  - Are enhanced porous cups in THA failing?

- **Post market surveillance of devices when new device features are added to market**
  - Vitamin E and anti-oxidant polyethylene

- **Comparative effectiveness research**
  - Which perform best over time: monoblock all-poly tibias or modular metal-backed tibias?
# Integrated Healthcare Systems MdEpiNet Contribution

## Clinical expertise
- Project selection and prioritization
- Study design and protocol development
- Interpretation of data
- Translating data into clinical practice

## Methodological expertise
- Project selection and design of studies
- Data collection and methods
- Implementation of studies
- Statistical analyses and interpretation of data
- Translating data into clinical practice
Keys to Success

- Data security, propriety, privacy and legal concerns
  - Data integrity/security
    - Data sources need to be accurate and validated
    - Minimum necessary data shared
    - Secure data transfer mechanisms
    - Healthcare systems to authorize all use of data
  - Privacy
    - Adherence to US privacy requirements/HIPAA
  - Distributed data network reduces these concerns
    - Centers have operational and physical control of data at all time
- Conflicts of interest stated and addressed
Keys to Success

- Healthcare systems need to be formalized and equal partner in MdEpiNet structure
  - Lead with academics strategic planning, project selection, study design, data analysis and interpretation, publications
  - Lead role in dissemination of findings/ translating evidence into clinical practice
  - Key partner in governance and decision making
Thank You