Kaiser Permanente Implant Registries: Enhancing Patient Safety and Quality of Care

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Southern California Permanente Medical Group
Background

Patient Registry

“an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.”

Background

• RCTs
  – Small sample sizes
  – Short/Limited follow-up
  – Specific inclusion/exclusion criteria
  – Limited exposures/treatments
  – Limited number of participating centers/academic centers
  – High internal validity

• Patient Registries
  – Large sample sizes
  – Longitudinal follow-up
  – Diverse patient groups
  – Multiple exposures/treatments in real world setting
  – Variety of participating centers/community based
  – High external validity
• Patient registries are ideal in situations where
  – Want real world applicability
  – Need large sample sizes to detect rare events
  – Need longitudinal follow-up
  – RCTs are not practical, feasible or ethical

• Use of patient registries
  – Describe current treatment and utilization patterns
  – Track and monitor longitudinal outcomes
  – Identify variations in treatment and outcomes
  – Identify risk factors associated with outcomes
  – Evaluate comparative effectiveness of treatments
  – Provide surveillance of adverse events for patient safety
  – Identify clinical best practices to improve quality of care
Kaiser Permanente Total Joint Registry

- **Total Joint Replacement (TJR) in the U.S.**
  - 700,000 total knees (TKA) and hip (THA)

- **Projected Volume 2030**
  (Kurtz et al., 2007; Khatod et al., 2008)
  - Primary TKA 673% increase, Revision 601%
  - Primary THA 174% increase, Revision 137%

- **Projected Annual Hospital Charges 2015**
  (Kurtz et al., 2007)
  - Primary THA $17.4 billion, TKA $40.8 billion
  - Revision THA $3.8 billion, TKA $4.1 billion
Kaiser Permanente Total Joint Registry

- Initiated in 2001
- Modeled after Swedish National Hip Registry
- Standardized documentation
  - Pre-op
  - Operative
  - Follow-up
- TJR database
  - Demographics
  - Surgical techniques
  - Implant characteristics
  - Outcomes
Kaiser Permanente Total Joint Registry

Data Sources
- Pre-op form
- Operative form
- Post-Op form
- Hospital
- Claims
- Membership
- Mortality

Data Acquisition & Quality
- Data mapping, quality and transport
  - Data entry shell
- Data cleaning & quality checks
  - Business Rules
  - Data extract, transfer and load
  - Data cleaning & quality checks

Data Aggregation & Storage

Total Joint Registry SQL Database
Domains
- Patient demographics
- Implant characteristics
- Surgical techniques
- Outcomes

SAS Analytics
- Data Extraction
- Data Mining
- Data queries
- Multivariate logistic regression
- Predictive Modeling
- Survival Analysis

Information Delivery
- Annual report
- Ad hoc requests
- Personalized profiles
- Web-based reports
- Risk calculator
- Research projects
- Recalls / advisories
• Quality control queries w/ chart review
  – Out of range values
  – Inconsistent values
  – Missing values

• Validation of procedure, diagnostic codes, implants
  – Independent administrative databases
  – Physician/OR logs

• Electronic screening algorithms w/ chart review validation of complications
  – Infections, DVT, PE and revisions
  – CDC/AHRQ guidelines
Kaiser Permanente Total Joint Registry

- MD/staff champions
- Site visits/road shows
- Chiefs’ meetings
- Symposium, internal and external
- Interactive Website, internal
- Physician profiles
- Risk calculators
- Annual report
- Abstracts/publications
- KP ideabook
- Newsletters, e-mails
### Expansion to Other Registries

#### Orthopedic
- ACL: 13,000
- Spine: 6,781
- Shoulder: 4,476
- Hip Fracture: 12,282

#### Cardiac
- ICD: 19,024
- Pacemaker: 45,722
- Heart Valve: 58,765
### Recall/Alert List - All Registries

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Manufacturer</th>
<th>Alert Type</th>
<th>FDA Class</th>
<th>Implant Type</th>
<th>Registry</th>
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<tr>
<td>10/21/2010</td>
<td>NexGen® Complete Knee Solution Stemmed Tibial Component</td>
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<td>Recall</td>
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<td>Smith and Nephew</td>
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<td>Base Plate</td>
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<td>Voluntary</td>
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</table>
Patient Monitoring During Recalls

DePuy ASR August 2010 Recall Tracking Database

SEARCH FOR: MRN  Last Name  ASR Update:  Go!

Instructions: Enter applicable information below in fields that are highlighted in white.

PATIENT INFORMATION

MRN: 1234567  Region: CO

SMITH  JANE

Sex: F  Race:

Age:

Phone:

ASR Update: 06/05/07  RIGHT

Inherited  Non-Member

Follow-up Facility:

Follow-up MD:

Risk Mgr:

TJR HIP SURGERIES

Facility: DVR  Surgeon: Jekyll

Date: 6/5/2007  Ospide: RIGHT

TJR Rev Date:

Scheduled Rev Date:

Implants:

ASR Flag:

BMI:

Patient Name: SMITH  JANE  MRN: 1234567  ASR Update: 06/05/07  RIGHT

PATIENT STATUS  CASE MANAGER LOG  BONE SCAN  HISTOPATHOLOGY  PAIN  ION SCAN  LAB  MRI  XRAY  DEPuy CLAIM INFO

Contact Date: 11/9/2010  Staff: CO

Case Manager Follow Up Date:  

Provider Appt Date: 12/8/2010

Are you having any pain around your hip area?  

Change in Pain Level?  

Pain Level:

Note:

seen in clinic 9/2/10, will need appt with Dr. Tuttle
Evaluate Longitudinal Outcomes

Survival Curve with 95% CL

<table>
<thead>
<tr>
<th>Survival Time (years)</th>
<th>Survival Probability</th>
<th>No. of Subjects</th>
<th>Event</th>
<th>Censored</th>
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<td></td>
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<td>0.98</td>
<td>4483</td>
<td>4% (178)</td>
<td>96% (4305)</td>
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<td>0.96</td>
<td>44818</td>
<td>2% (748)</td>
<td>98% (44070)</td>
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Logrank p < .0001
Surgical Site Infection Surveillance

TOTAL JOINT REPLACEMENT REGISTRY
Statistical Process Control (SPC) Charts

TOTAL HIP SSI RATES
2008Q3 - 2011Q2

HIP SSI / TOTAL HIP PROCEDURES

QUARTER:

- Based on Preliminary data
- NHSN Benchmark: 1.4%
Risk Adjusted Medical Center Variation

Deep Infection Rate among Primaries, with Observed to Expected Case Ratio (Hips)
# Total Joint Replacement

## Surgeon Profile Report

Op Date between May 2000 to March 2009

### Demographics

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<thead>
<tr>
<th>Age Category</th>
<th>Surgeon #</th>
<th></th>
<th>Facility #</th>
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<th>Region #</th>
<th></th>
<th>National #</th>
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<td>1</td>
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<td>13</td>
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<td>71</td>
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<td>407</td>
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<td>40-49</td>
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<td>5.5%</td>
<td>86</td>
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<td>821</td>
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<td>1860</td>
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<td>50-59</td>
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<td>142</td>
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<td>7895</td>
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<td>2895</td>
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<td>90 and &gt;</td>
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<td>5</td>
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<td>39</td>
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<td>100.0%</td>
<td>905</td>
<td>100.0%</td>
<td>10909</td>
<td>100.0%</td>
<td>26449</td>
<td>100.0%</td>
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<tr>
<th>Gender</th>
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<th>Region #</th>
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<th>National #</th>
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<tr>
<td>Male</td>
<td>74</td>
<td>33.6%</td>
<td>371</td>
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<td>42.7%</td>
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<td>534</td>
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<tr>
<td><strong>Total</strong></td>
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<td>905</td>
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<td>10909</td>
<td>100.0%</td>
<td>26449</td>
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<th>ASA Score</th>
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<td>393</td>
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<td>172</td>
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<td>15942</td>
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</table>
## Total Joint Replacement
### Surgeon Profile Report

**Op Date between May 2000 to March 2009**

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#### DVT

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<td>%</td>
<td>#</td>
<td>%</td>
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<td><strong>Total</strong></td>
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<td><strong>905</strong></td>
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#### Infection

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<tbody>
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<td>%</td>
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<td>%</td>
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<tr>
<td>No</td>
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<tr>
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<tr>
<td><strong>Total</strong></td>
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<td><strong>100.0%</strong></td>
<td><strong>905</strong></td>
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#### Infection Type

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<td>Superficial</td>
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#### Pain

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<tbody>
<tr>
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<td>Mean</td>
<td>St Dev</td>
<td>#</td>
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<tr>
<td>3wks Post-Op</td>
<td>89</td>
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<td>4wks-8mths Post-Op</td>
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<td>1.5</td>
<td>1.6</td>
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<tr>
<td>1 Year</td>
<td>44</td>
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#### Satisfaction

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<tbody>
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<td>Mean</td>
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<tr>
<td>3wks Post-Op</td>
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<td>4wks-8mths Post-Op</td>
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<tr>
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<td>1.0</td>
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</tbody>
</table>

#### Revision Rates

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Facility</th>
<th>Region</th>
<th>National</th>
</tr>
</thead>
<tbody>
<tr>
<td>#</td>
<td>%</td>
<td>#</td>
<td>%</td>
</tr>
<tr>
<td>No Revision</td>
<td>214</td>
<td>97.3%</td>
<td>879</td>
</tr>
<tr>
<td>Revised</td>
<td>6</td>
<td>2.7%</td>
<td>26</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>220</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>905</strong></td>
</tr>
</tbody>
</table>
Identification of Target Populations: Prevention Video
Comparative Effectiveness

### Survival Curve with 95% CL

**Number at Risk (years)**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allograft</td>
<td>2707</td>
<td>1330</td>
<td>496</td>
<td>82</td>
<td>25</td>
</tr>
<tr>
<td>PT BTB</td>
<td>2152</td>
<td>1247</td>
<td>654</td>
<td>239</td>
<td>59</td>
</tr>
<tr>
<td>Quad H/S Tendon</td>
<td>2054</td>
<td>993</td>
<td>354</td>
<td>68</td>
<td>25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>No. of Subjects</th>
<th>Event</th>
<th>Censored</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allograft</td>
<td>2707</td>
<td>1% (36)</td>
<td>99% (2671)</td>
</tr>
<tr>
<td>PT BTB</td>
<td>2152</td>
<td>1% (19)</td>
<td>99% (2133)</td>
</tr>
<tr>
<td>Quad H/S Tendon</td>
<td>2054</td>
<td>1% (24)</td>
<td>99% (2030)</td>
</tr>
</tbody>
</table>

Logrank p = 0.0004
## Identification of Risk Factors

### THA Revision Risk Factors. Hazard Ratios & 95% Confidence Intervals

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis Yes vs. No</td>
<td>0.63</td>
<td></td>
</tr>
<tr>
<td>Race Hispanic vs. White</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td>Femoral Head Size &lt;36mm vs. ≥36mm</td>
<td>1.76</td>
<td></td>
</tr>
<tr>
<td>Metal on Conventional vs. Metal on Crosslink</td>
<td>1.56</td>
<td></td>
</tr>
</tbody>
</table>

### TKA Revision Risk Factors. Hazard Ratios & 95% Confidence Intervals

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 10 year increments</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>Diabetes Yes vs. No</td>
<td>1.32</td>
<td></td>
</tr>
<tr>
<td>Race Black vs. White</td>
<td>1.82</td>
<td></td>
</tr>
<tr>
<td>Bilateral Yes vs. No</td>
<td>0.57</td>
<td></td>
</tr>
<tr>
<td>Patella Unresurfaced vs. Resurfaced</td>
<td>2.09</td>
<td></td>
</tr>
<tr>
<td>Platform Rotate-LCS vs. Fixed</td>
<td>2.01</td>
<td></td>
</tr>
</tbody>
</table>
Revision Risk Calculators

TJR Total Knee

Age: 

Gender: 

Weight: 

Height: 

Diabetes: 

Osteoarthritis: 

Inflammatory Arthritis: 

Post Traumatic Arthritis: 

Rheumatoid Arthritis: 

Osteonecrosis: 

Your risk of a revision is within 5 years:

Calculate

Clear

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Changes in Practice: THAs

Survival Curve with 95% CL

- Survival Probability vs. Survival Time (years)
- Note: Cases with infection were excluded from this analysis.

% Usage

- >=36mm
- 32mm
- 28mm

2001 to 2009 Q1
Changes in Practice: TKAs

Survival Curve with 95% CI

Log-rank p < .001

Note: All cases of revision due to infection were excluded from this analysis.

% Usage

2001 2002 2003 2004 2005 2006 2007 2008

Fixed PS
Fixed CR
Mobile PS
Mobile LCS
Mobile CR
THA Revision Rates/Burden

Survival Curve with 95% CI

Survival Probability vs. Survival Time (years)

Log-rank p < .001

% Of Total Procedures Performed

Revision THA
Keys to Success

- MD involvement at all stages
- Direct feedback to clinical staff and MDs
- Minimal burden to frontline staff
- Leverage existing databases
- Rigorous quality control mechanisms and validation of outcomes
Recommendations for Future

• Registry integration into workflow
  – Customizable EHR registry modules
  – Bi-directionality with EHRs
  – Clinical decision tools and reminders
• Automated postmarket surveillance for adverse event detection
• Patient centered virtual visits
• National and International collaborations to leverage existing registries, EHRs, and large administrative databases (e.g., International Consortium)
Value of Registries

• Provide quality, relevant clinical information to physicians, hospitals, patients, industry, regulators in real time based on real world experience

• Continuous Quality Improvement
  – Identification of variation in practices and outcomes
  – Identification and dissemination of clinical best practices enhances quality of care
  – Clinician ownership is a critical factor in change

• Patient Safety
  – Identification of patient risk factors
  – Use in recalls, advisories, and adverse event surveillance

• Comparative effectiveness
• The Permanente Journal registry web site: