FORCE-TJR
2015 Annual Report

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Executive Summary

The 2015 FORCE-TJR Annual Report celebrates two major milestones: (1) the successful completion of the AHRQ funding period and (2) the introduction of the new FORCE VALUE management system.

1. Celebrating initial FORCE-TJR accomplishments

FORCE-TJR exceeded the original goals of the AHRQ award (2010-2015). We summarize the major research and registry accomplishments that serve patients, surgeons, hospitals, insurers, implant manufacturers, and policy leaders. Our Bibliography includes more than 30 publications (with dozens more in the queue), and more than 100 presentations at scientific meetings across the globe. In the past year, we received five (5) federal research awards to continue our innovative comparative effectiveness research.

Beyond research, clinician and hospitals use the FORCE-TJR data and infrastructure to improve quality of care. Specifically:

- FORCE-TJR is the first US national cohort of TJR patients with risk-adjusted outcome norms for representative, diverse practices (e.g., urban and rural, high and low volume), and patients of all ages. Because the new CMS Comprehensive Joint Replacement program was informed by the FORCE-TJR risk factors and adopted identical outcome measures, FORCE-TJR benchmarks are critical for CJR hospitals.

- Hospitals and surgeons use the FORCE-TJR infrastructure to monitor quality of care, including readmissions and complications across 90 days that occur at any hospital and patient-reported pain relief and functional gain.

- FORCE-TJR is designated a CMS Qualified Clinical Data Registry so that reporting hospitals/surgeons receive incentive payments from CMS quality programs.

- FORCE-TJR data submission meets the American Board of Surgeons maintenance of certification requirements for orthopedic surgeons.

- FORCE-TJR is collaborating with FDA to monitor implant survivorship, as FORCE-TJR matches implant components to the international library.

2. Introducing FORCE VALUE management system

We are excited to introduce the interactive FORCE VALUE management system to guide optimal patient care across the episode of surgery and recovery. The core FORCE-TJR attributes of expert data collection, real-time reports, and risk-adjusted benchmarks are included to serve surgeons and hospitals managing episodes of care from hospital to home. In addition, new process monitoring and improvement tools will assure efficient post-discharge utilization management in the new bundled payment environment. Finally, these tools go beyond TJR to other high volume orthopedic conditions including shoulder replacement and spine.

Please contact us to discuss how FORCE-TJR and FORCE VALUE management can support you!

Sincerely,

Patricia D. Franklin, MD MBA MPH

David C. Ayers, MD
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Drexel University College of Medicine (Hip Society)
University of Massachusetts Medical School
Hartford Hospital (AAHKS)
Food and Drug Administration (FDA)
National Institutes of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Food and Drug Administration (FDA)
Arcadia University
Center for Medicare and Medicare Services (CMS)
Citizens for Patient Safety
DePuy Orthopaedics, A J&J company
Biomet, Inc.

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FORCE-TJR Accomplishments (2010-2015)

The AHRQ award explicity stated that FORCE-TJR should serve both as a TJR quality and outcomes registry and as a comparative effectiveness research program. FORCE-TJR went beyond these goals to inform CMS payment policy and to build generalizable PRO implementation strategies.

Policy informed by FORCE-TJR analyses

- **CMS/CMMI Value-based payment in TJR.** FORCE-TJR analyses informed the risk-adjustment and outcome measures for the 2016 CMS/CMMI implementation of the mandatory TJR value-based payment system in 67 US metropolitan areas (Comprehensive Care for Joint Replacement program). Comprehensive risk-adjustment for readmissions, complications, and patient-reported outcomes is essential to assure equitable comparisons across hospitals and to support uniform patient access to TJR. In addition, the FORCE-TJR cohort was used to validate brief patient-reported measures (HOOS/KOOS JR). Thus, the FORCE-TJR produces risk-adjusted, national norms for the two CJR patient-reported outcome measures: HOOS/KOOS JR and the full HOOS/KOOS.

- **US/CMS and UK comparison of patient-reported outcomes in TJR.** FORCE-TJR data were highlighted in a CMS-sponsored comparison of patient-reported outcomes between the US and United Kingdom for obese and non-obese patients. The analyses were presented at the Healthcare Datapalooza in June 2015.

- **FDA and MDEpiNet.** FORCE-TJR, in collaboration with Weill Cornell and other regional US registries, will form an orthopedic network to monitor TJR implant outcomes. Uniquely, FORCE-TJR will assess the role of patient-reported pain and function through a new phone APP to monitor early implant failure.

- **International Consortium of Health Outcome Measures (ICHOM).** The FORCE-TJR PI (Franklin) lead an international osteoarthritis and TJR workgroup of experts to endorse an outcome measure set and collection methods. Of note, the ICHOM Osteoarthritis/TJR measure set parallels the core FORCE-TJR measures.

PRO Implementation expertise for TJR and beyond

The collection of complete longitudinal outcome data is critical in this era of value and quality measurement. FORCE-TJR’s unique direct-to-patient outcome methods, refined web-based infrastructure, and novel risk-adjusted outcome reporting system achieved 8e% complete data over the first year. No other US registry reports this level of completeness. While the International Society of Arthroplasty Registries expects over 70% long-term data for sufficient data quality, other US registries are reporting 20-40% response. Specific FORCE-TJR products to improve PRO collection methods include:

- **PRO implementation framework for all conditions.** With funding from AHRQ, and in collaboration with Academy Health’s Electronic Data Methods team and other US registries, FORCE-TJR investigators developed a framework to guide implementation of PROs. Based on interviews with more than 30 PRO leaders in medical, surgical, pediatric, and behavioral health fields, this framework guides planning and implementation for clinicians and hospitals.

- **APP for PRO collection.** With AHRQ and FDA funding, the FORCE-TJR team is converting direct-to-patient PRO capture through a simple phone APP. Patient and clinician focus-groups informed the usability and design. Early APP testing in underway with test deployment this year.

- **PROs in pharmaceutical outcomes.** FORCE-TJR will support the PRO analyses in the team implementing the newly funded PCORI pragmatic trial to assess comparative effectiveness of three different anti-thrombotic prophylactic medications in TJR patients.

FORCE-TJR Registry accomplishments

Since October 2010, the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) registry has been a US leader in TJR outcome measurement. By fall 2015, the original AHRQ-
funding goals were achieved with data from more than 25,000 patients collected from a representative sample of more than 200 surgeons in 28 states. Sites and surgeons were selected to assure that the FORCE-TJR national norms represent the profile of patients and surgeons in the US today. Thus, FORCE-TJR has the only risk-adjusted, US national benchmarks for peri-operative adverse events, patient-reported outcomes, and early implant failure in all US patients. Of note, these are the only national outcome data available for the 48% of TJR patients who are under 65 years of age. The FORCE-TJR data collection and analytic methods informed the recently announced CMS mandatory bundled payment program for TJR. While this report includes early data and lessons, registry data become even more valuable over time as the natural history of the patient and implant outcomes emerge. Thus, FORCE-TJR’s foundation will inform TJR best practice and outcomes for years to come.

FORCE-TJR is a comprehensive registry generating high value TJR care and new knowledge of best practice guidelines to meet the goals of diverse stakeholders.

1. **For Patient Care Delivery:**
   While electronic medical records systems struggle to collect, score, and trend patient-reported outcomes (PROs) over time, FORCE-TJR offers real-time scoring and pain and function trends. Real-time patient-reported outcome scoring allows the patient and surgeon to view trended pain and function (both decline and improvement) before and after TJR.
   - Before surgery, patient pain and function scores can be compared to national TJR norms to guide timing for surgery.
   - After TJR, pain relief and functional gain can be quantified and care tailored to support optimal recovery.

   Finally, with AHRQ funding, FORCE is developing a phone APP to guide shared decision-making when faced with a TJR decision. TJR patients express enthusiastic support for web-based and phone data support methods:
   
   > "When he [the surgeon] saw the PRO survey, he saw how my function was, how bad it was... without the survey he wouldn't have known." Patient, age 72, TKR, PA
   > "It's important to participate [in FORCE-TJR] so that people who have knee replacements in the future can benefit from my experience." Patient, age 53, TKR, MA

2. **For Surgeons and Hospital Quality Monitoring:**
   FORCE-TJR includes benchmarks that match those measures included in the CMS/CMMI pilot proposal (CJR). Sites in the 67 mandatory bundled payment regions can receive reimbursement for collecting FORCE outcome measures.
   - The revised FORCE-TJR secure MD Website delivers quarterly outcome reports to answer three critical questions that previously surgeons could not answer: (1) How do my patients’ pre-operative risk profiles compare to other surgeons? (2) How does the timing of my patients’ surgery, as described by pain and functional limitations, compare to national practice? (3) Is the degree of pain relief and improved function in my patients comparable to the national norm?

   Orthopedic surgeons express appreciation for these methods:
   
   > "Again, thank you for allowing us to participate in what I feel will be of significant value to the quality of care that joint replacement surgery can offer to the public. Also, all three of us, and our nurse manager, thank you for managing this effort so effectively." Surgeon, OK.

3. **For Insurer Value Monitoring:**
   - CMS initiated public reporting of post-TJR readmissions and complications in 2014. In collaboration with AAHKS, FORCE-TJR significantly improved the risk-adjustment readmission models so that members receive risk-adjusted comparative reports to support quality improvement before these data are publicly reported.
   - Private insurers anticipate using pre-operative PROs as one way to determine appropriate use of TJR. FORCE-TJR is deploying new decision-support tools to guide surgeons and patients in the clinic before payer review.

4. **For FDA and industry implant monitoring:**
   - The FORCE-TJR data provide early post-marketing surveillance data. In contrast to registries that solely define
Implant failure as revision surgery, FORCE-TJR surveillance includes post-TJR implant complications and patient-reported pain, both events that precede revision surgery. FORCE is now monitoring implant performance using direct-to-patient assessment strategies for implant manufacturers.

- **Implant evaluation.** The comprehensive FORCE-TJR clinical and patient data are merged with the international library of implant design and materials to evaluate outcomes associated with varied implant characteristics. Outcomes of specific implants are now being monitored.

**FORCE-TJR Comparative Effectiveness Research**

**Generating new knowledge to guide best practice: FORCE-TJR comparative effectiveness research.**

- **Defining a practical, but precise, brief PRO.** To minimize patient response burden, ideally, a subset of PRO items will reliably generate knee and hip PRO scores. However, it is important to maintain the specificity of current measures for pain and function in any brief form. As a first step toward deploying brief surveys, FORCE-TJR data validated the recently developed HOOS JR and KOOS JR. (See Bibliography). Second, a new 2016 AHRQ award to the FORCE-TJR team will develop and validate brief knee and hip scores to monitor function and pain and retain the specificity of the long forms. The resulting surveys will be available next year to efficiently collect pain and function while maintaining specificity and comparability to legacy (long) versions.

- **Defining patients at risk for readmission.** The sub-group of patients with early readmissions also has poorer functional gain. Identifying this high-risk patient group is important to reduce morbidity and financial risk in an era of bundled payments. FORCE-TJR publications in the Journal of Bone and Joint Surgery and other orthopedic journals are disseminating methods to define high-risk patients and analyze comparable outcomes (see Bibliography). These methods were recently presented at the AAOS-CMS summit on patient-reported outcomes to guide the CMS bundled payment pilot program.

- **Defining sub-groups of patients at risk for early revision.** Using implant data and patient-reported outcomes, FORCE-TJR is evaluating outcomes of patients with different implant components and fixation techniques. FDA funding will extend the implementation of new methods.

- **Defining outcome benchmarks for patients under 65 years of age.** Some believe the shift to a younger TJR population suggests a less complex patient pool, but FORCE-TJR data dispute this assumption. Younger patients report the same, or greater, joint-specific and global pain and decreased function pre-operatively compared to older adults. In addition, patients under 65 years of age are more obese and more likely to smoke as compared to older patients. For the first time, FORCE-TJR has national norms for pre-operative and post-operative pain and function in these working aged adults who are the fastest growing users of TJR.

- **Optimal patient timing of TKR and THR.** In contrast to recent public reports suggesting that one-third of TKR procedures may be “inappropriate,” FORCE-TJR’s patient-reported data illustrate that the vast majority of today’s TJR patients have advanced disability and severe knee or hip pain at the time of surgery. However, approximately 8% of TKR and THR patients report few symptoms at the time of TJR prompting further exploration about surgical indications and appropriateness in this sub-group.

- **Defining impact of co-existing lumbar spine and contralateral joint disease on outcomes.** The burden of musculoskeletal comorbidities, specifically moderate or severe pain in the lumbar spine and non-operative hips and knees, negatively affects self-reported function at 6 months after both TKR and THR. Future public comparisons of PROs after TJR must adjust for co-existing musculoskeletal conditions.
Future FORCE-TJR research
In the next years, using 2-5 year outcomes on 25,000 FORCE-TJR patients, we will evaluate the interactions among patient-comorbidity-implant factors in key patient sub-groups to define tailored best practices associated with persistent post-operative pain relief, functional gain, and minimal post-TJR adverse events. FORCE-TJR cohort patients agree to annual assessments for the next 20 years.

FORCE-TJR Bibliography
The current FORCE-TJR Bibliography is included in Appendix 1. Since the initial overview paper published in JAMA, 30 manuscripts have been published (with additional papers under review) in diverse journals serving primarily orthopedic surgeons and research methodologists. In addition, five ancillary research grants were awarded from AHRQ, PCORI, FDA, and NIH and six more applications are under review. Finally, more than 100 international and national peer-reviewed abstracts have been presented at diverse professional meetings serving orthopedics, rheumatology, public health, health services research, psychometrics, and informatics.

FORCE-TJR Membership Model will expand patient data
To assure sustainability of the FORCE-TJR infrastructure, paid FORCE-TJR memberships are now open to US and international hospitals and surgeons committed to high-value care. In the first months after offering membership, the number of surgeons participating in FORCE-TJR grew by 46%, and membership continues to climb. The first international participant just joined. Member hospitals and surgeons receive the same risk-adjusted benchmarks as the initial FORCE-TJR sites while contributing larger numbers of TJR procedures from even more diverse settings. The FORCE-TJR cohort continues to grow!

The future: FORCE VALUE Management System
The introduction of bundled payment programs brings new responsibilities and risks for hospitals and affiliated orthopedic surgeons. Hospitals and surgeons are collaborating to manage the total care and resource use across the 90 days of the surgical episode. Pre-operative risk-profiles are the first step in selecting and preparing patients for TJR surgery, tailoring in-hospital and post-discharge care, and guiding rehabilitation. The original FORCE-TJR model has been adapted in three important ways to meet these new demands, for hip and knee replacement, shoulder, and spine care.
The FORCE VALUE Management System includes:

1. REAL-TIME PRE-OPERATIVE risk factor profiles to tailor patient care and improve outcomes.
   a. Inform shared decisions: Patient-reported pain and function guide timing and use of TJR.
   b. Tailor peri-operative and post-discharge care: Medical and musculoskeletal risk profiles inform surgical preparation and peri-operative care to minimize complications.
   c. Optimize in-home post-discharge care and rehabilitation needs.

2. EPISODE MANAGEMENT: In hospital and post-discharge monitoring reports to minimize emergency room use or hospital readmission.
   a. Manage across the 90 day episode with new web-based surveys to integrate monitoring data from hospital to home and rehabilitation.
   b. Prioritize staff coordination activities using new reports based on known risk factors, in-hospital experience, and patient and clinician reports.

3. ASSURE BEST PRACTICES: FORCE supports best practices in two ways:
   a. Risk-adjusted national comparative outcome reports will anticipate your performance in public reporting and CMS initiatives.
   b. FORCE consultation and training for your clinical team to assure complete pre-operative and post-operative data collection, including optimal use of the new real-time episode monitoring tools.
Highlights from new FORCE-TJR research

In the following pages, we present brief summaries of recently reported findings from FORCE-TJR research, including:

- PRO Implementation Framework to guide complete data capture in orthopedics and other conditions
- Post-TJR readmissions are associated with poorer global function after TJR
- After successful TKR, patients achieve pain relief in their non-operative hips and knee
- Post-TKR benefits demonstrated across diverse pre-operative profiles
- Today’s TJR patients are younger, heavier, and just as disabled
- Patients with high BMI report significant functional improvement after TJR

In addition, we include a new summary document on ‘How to Select a TJR Registry’: guidelines from the FORCE-TJR team.
PRO Implementation framework to guide successful capture

As the value of patient reported outcomes (PROs) expands, a framework to guide the planning, collection, and use of PROs to serve multiple goals and stakeholders is needed. To define this framework, registry leaders from FORCE-TJR, SCOAP (spine), Kaiser Permanente, and California identified diverse clinical, quality, and research settings where PROs have been successfully integrated into care and routinely collected and analyzed. Unifying themes emerged from these successful examples in behavioral health, primary care, oncology, orthopedics, pediatric gastroenterology, and neurology. The proposed framework will guide future PRO implementation efforts across learning healthcare systems to assure that complete PROs are captured at the correct time, and with associated risk factors, to generate meaningful information to serve diverse stakeholders. (Funded by AHRQ through Academy Health Electronic Data Methods.)

1. **WHY PROs?**
   - Multiple stakeholders value the collection and use of PROs, but hold different goals. In a true learning health system, PRO collection will meet the value proposition for all stakeholders, leading to efficient collection with the greatest utility of research-quality data within the healthcare delivery systems.

2. **WHO?**
   - Individual patients in the clinic or populations with specific conditions.

3. **WHERE/WHEN?**
   - PRO captured at time of patient care or directly from patient at home to assure complete and timely data.

4. **WHAT?**
   - Global and/or condition-specific PROs to quantify symptoms and health status plus relevant risk factors.

5. **HOW?**
   - PRO capture and storage supported by EMR portal or web- or phone-based direct to patient systems. Reminders to assure complete PRO capture.

6. **INFORMING PRACTICE**
   - PRO data scored, risk-adjusted, and analyzed to trend over time and/or compare to external benchmarks at individual or aggregate levels.

   - PROs at every office visit to monitor changes over time.
   - Pre-PRO in office; post-PRO at uniform intervals to monitor improvement after treatments (office or home).
   - Pre-PRO in office; post-PRO at uniform intervals to monitor improvement after treatments (office or home).
   - PRO collected at uniform intervals; annual health assessment and/or to meet CER goals.

   - Condition-specific PRO at office visits to monitor symptoms and health.
   - Condition-specific and/or global health PROs; risk factors; national benchmarks.
   - Condition-specific and/or global health PROs; risk factors; national benchmarks.
   - Global health PRO +/- specific condition PRO; risk factors; national benchmarks.

   - Web or EMR portal for PRO capture; real-time scoring system; stored in EMR.
   - Web or EMR portal PRO capture; reminder systems; stored in EMR.
   - Web or EMR portal PRO capture; reminder systems; stored in EMR; export to payer.
   - Web or EMR portal capture; reminder systems; stored in EMR, PHR, or research data.

   - Individualized scored, trended PRO reports.
   - Aggregate risk-adjusted PROs compared to benchmarks.
   - Aggregate pre- and post-TJR scores within acceptable PRO ranges.
   - Aggregate physical & emotional health with aging; population research.
Post-TJR readmissions are associated with poorer functional gain after TJR

CMS is publicly reporting 30 day readmission rates after total joint replacement (TJR) by hospital and is planning to add patient-reported function and pain. On average, 5% of TJR patients are readmitted to the hospital after surgery for medical or orthopedic-related issues. FORCE-TJR data for primary TJR patients from over 150 surgeons practicing in 22 states and who were over 65 years were identified. Overall 4.7% of patients were readmitted; 2.0% due to limb related diagnoses. Readmitted patients had significantly greater number of medical comorbidities; more severe OA in non-operated knees and hips; were more likely to smoke; and have poorer pre-TJR function (all p<0.05). The FORCE-TJR readmission model predicted 80-85% of readmissions. See figures below.

CMS patients with readmissions within 30 days have significantly poorer mean global function at 6 months than patients without readmission. More readmitted patients had poor global function (PCS<30= 14%) as compared to patients with no readmission (8%; p<0.008) but knee/hip function was similar in both groups. Joint pain improvement did not differ by readmit status. These data support the importance of joint-specific PRO measures to assess TJR outcomes in quality of care programs.

Figure 1. Primary TKR risk model predicts 80% of Readmissions

Patients who were readmitted were more likely to report poor global function at 6 months after TJR.

Figure 2. Primary THR risk model predicts 85% of Readmissions

After successful TKR, patients achieve pain relief in their non-operative hips and knee

To assess the effect of successful TKR on short-term pain relief of the non-operated joints (hips and contralateral knee), we evaluated the change in pain in each joint after TKR. We found that patients who undergo TKR may achieve pain relief in their non-operated hip and knee joints. Those patients who report moderate to severe pain levels are more likely to experience improvement, in up to 78% of the cases. It is possible that these patients are able to unload the remaining non-operated joints at 6 months and rely more on their TKA during their activities of daily living.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Reported no Pain Prior to TKR</th>
<th>Reported Worsening Pain (was pain free prior to TKR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contralateral hip</td>
<td>61%</td>
<td>12%</td>
</tr>
<tr>
<td>Ipsilateral Hip</td>
<td>50%</td>
<td>11%</td>
</tr>
<tr>
<td>Contralateral Knee</td>
<td>14%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Approximately 15% of the patients who were pain free in their non-operative joints developed worsening pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>% of Patients with Improvement</th>
<th>Chi-square</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contralateral Hip HOOS Baseline Pain Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>49%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>77%</td>
<td>55.98</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Severe</td>
<td>86%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patients with severe preoperative pain in their contralateral hip had the greatest chance of improvement

<table>
<thead>
<tr>
<th>Variable</th>
<th>% of Patients with Improvement</th>
<th>Chi-square</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ipsilateral Hip HOOS Baseline Pain Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>59%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>81%</td>
<td>54.39</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Severe</td>
<td>89%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patients with severe preoperative pain in their ipsilateral hip had the greatest chance of improvement

<table>
<thead>
<tr>
<th>Variable</th>
<th>% of Patients with Improvement</th>
<th>Chi-square</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contralateral Knee KOOS Baseline Pain Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>35%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>63%</td>
<td>239.81</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Severe</td>
<td>79%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Post-TKR benefits demonstrated across diverse pre-operative profiles

We examined 6-month change in pain, function, and quality of life (QOL) by pre-surgery pain and function profiles. More than 91% of TKR patients report significant pain and/or limited function before surgery. We found that patients with high pain and poor function pre-TKR had the greatest mean improvement in pain relief and function 6-month post-TKR. Also, while TKR patients with little pain and high function at baseline had the lowest mean change in pain and function, they reported better absolute outcomes 6-month post-TKR. Finally we found that there was much improvement in QOL across all groups by 6 month post-TKR.

<table>
<thead>
<tr>
<th>Clinical Characteristics by Pre-TKR</th>
<th>Group 1 Little Pain / High Function n=234 (5%)</th>
<th>Group 2 Little Pain / Poor Function n=173 (4%)</th>
<th>Group 3 High Pain / High Function n=718 (16%)</th>
<th>Group 4 High Pain / Poor Function n=3,288 (75%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain and Function</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain &amp; Function Status 6-mth Post-TKR</td>
<td>Remained in Same Classification Group</td>
<td>85%</td>
<td>25%</td>
<td>11%</td>
</tr>
<tr>
<td></td>
<td>Optimal Improvement &gt; to Little Pain-High Function</td>
<td>NA</td>
<td>65%</td>
<td>79%</td>
</tr>
<tr>
<td></td>
<td>Worst Decline &gt; to High Pain-Poor Function</td>
<td>4%</td>
<td>6%</td>
<td>7%</td>
</tr>
<tr>
<td>6-month Change in Pain</td>
<td>Pain, KOOS Mean (SD)-Pre</td>
<td>80.6 (7.8)</td>
<td>79.4 (7.5)</td>
<td>54.0 (11.3)</td>
</tr>
<tr>
<td></td>
<td>Pain, KOOS Mean (SD)-Post</td>
<td>88.8 (13.1)</td>
<td>89.8 (11.4)</td>
<td>84.4 (14.5)</td>
</tr>
<tr>
<td></td>
<td>Change over 6 months Mean (SD)</td>
<td>8.2 (14.6)</td>
<td>10.5 (13.0)</td>
<td>30.4 (16.7)</td>
</tr>
<tr>
<td></td>
<td>Unadjusted Mean Differences</td>
<td>REF</td>
<td>2.3</td>
<td>22.2</td>
</tr>
<tr>
<td></td>
<td>Unadjusted Standardized Differences, ES*</td>
<td>REF</td>
<td>0.1</td>
<td>0.3</td>
</tr>
<tr>
<td>6-month Change in Function</td>
<td>Function, SF36 PCS, Mean (SD)-Pre</td>
<td>47.4 (4.7)</td>
<td>34.0 (4.4)</td>
<td>44.5 (3.6)</td>
</tr>
<tr>
<td></td>
<td>Function, SF36 PCS, Mean (SD)-Post</td>
<td>49.9 (7.5)</td>
<td>44.0 (8.5)</td>
<td>49.4 (6.9)</td>
</tr>
<tr>
<td></td>
<td>Change over 6 months Mean (SD)</td>
<td>2.5 (7.8)</td>
<td>10.0 (7.8)</td>
<td>4.8 (6.9)</td>
</tr>
<tr>
<td></td>
<td>Unadjusted Mean Differences</td>
<td>REF</td>
<td>7.5</td>
<td>2.3</td>
</tr>
<tr>
<td></td>
<td>Unadjusted Standardized Differences, ES*</td>
<td>REF</td>
<td>0.7</td>
<td>0.1</td>
</tr>
<tr>
<td>6-mth Post-TKR Self-Evaluated Transitions</td>
<td>Better Health compared to 1 year ago-</td>
<td>60%</td>
<td>53%</td>
<td>62%</td>
</tr>
<tr>
<td></td>
<td>More Capable everyday physical activity</td>
<td>79%</td>
<td>79%</td>
<td>82%</td>
</tr>
<tr>
<td></td>
<td>More able to accomplish daily work</td>
<td>79%</td>
<td>78%</td>
<td>78%</td>
</tr>
<tr>
<td></td>
<td>Better Health compared to before surgery</td>
<td>60%</td>
<td>56%</td>
<td>63%</td>
</tr>
<tr>
<td>Quality of Life (QOL) Issues Pre- and Post-TKR</td>
<td>Awareness Knee Problem Daily/Constantly-Pre</td>
<td>87%</td>
<td>92%</td>
<td>99%</td>
</tr>
<tr>
<td></td>
<td>Awareness Knee Problem Daily/Constantly-Post</td>
<td>46%</td>
<td>52%</td>
<td>55%</td>
</tr>
<tr>
<td></td>
<td>Pain Frequency Daily/Always-Pre</td>
<td>47%</td>
<td>55%</td>
<td>94%</td>
</tr>
<tr>
<td></td>
<td>Pain Frequency Daily/Always-Post</td>
<td>19%</td>
<td>16%</td>
<td>28%</td>
</tr>
</tbody>
</table>
Today's TJR patients are younger, heavier, and just as disabled

At the time of TKR and THR, younger (<65) patients have fewer medical illnesses, but higher rates of obesity and smoking as well as lower mental health scores compared to older (>65) patients.

Younger patients have the same or greater joint specific and global functional impairment compared to older patients, which suggest that surgeons use comparable standards for selecting TKR and THR candidates in younger and older adults.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>THR Patients</th>
<th>TKR Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (% female)</td>
<td>Age &lt;65</td>
<td>Age ≥65</td>
</tr>
<tr>
<td></td>
<td>47.5</td>
<td>52.5</td>
</tr>
<tr>
<td>BMI (mean )</td>
<td>29.9</td>
<td>28.5</td>
</tr>
<tr>
<td>Race: nonwhite (%)</td>
<td>9.7</td>
<td>5.3</td>
</tr>
<tr>
<td>Smoking status (%)</td>
<td>Age &lt;65</td>
<td>Age ≥65</td>
</tr>
<tr>
<td>current</td>
<td>47.2</td>
<td>43.4</td>
</tr>
<tr>
<td>past</td>
<td>33.7</td>
<td>47.5</td>
</tr>
<tr>
<td>never</td>
<td>21.4</td>
<td>13.7</td>
</tr>
<tr>
<td>Baseline sf-36 PCS (mean)</td>
<td>31.2</td>
<td>32.5</td>
</tr>
<tr>
<td>Baseline sf-36 MCS (mean )</td>
<td>48.4</td>
<td>51.5</td>
</tr>
<tr>
<td>Charlson comorbidities index (%)</td>
<td>Age &lt;65</td>
<td>Age ≥65</td>
</tr>
<tr>
<td>0</td>
<td>66.0</td>
<td>49.1</td>
</tr>
<tr>
<td>1</td>
<td>17.8</td>
<td>21.1</td>
</tr>
<tr>
<td>2-5</td>
<td>8.4</td>
<td>12.0</td>
</tr>
<tr>
<td>&gt;=6</td>
<td>8.4</td>
<td>17.9</td>
</tr>
<tr>
<td>Pain in non-operative hip/knee joints (%)*</td>
<td>37.6</td>
<td>35.7</td>
</tr>
</tbody>
</table>

*Based on the HOOS/KOOS
Patients with high BMI report significant functional improvement after TJR

At 6 months after THR, all patients reported significant functional gains although patients with BMI>35 had lower mean functional gain than those with BMI≤35. All patients reported excellent pain relief.

At 6 months after TKR, severely obese patients (BMI>35) reported improvements in both pain and function equal to or greater than patients with BMI≤35.

<table>
<thead>
<tr>
<th></th>
<th>THR Patients</th>
<th>TKR Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>6 month</td>
</tr>
<tr>
<td>%</td>
<td>SF Physical function (Mean)</td>
<td>%</td>
</tr>
<tr>
<td>Under/normal weight</td>
<td>26%</td>
<td>32.4</td>
</tr>
<tr>
<td>Overweight</td>
<td>37%</td>
<td>32.7</td>
</tr>
<tr>
<td>Obese</td>
<td>22%</td>
<td>30.2</td>
</tr>
<tr>
<td>Severely obese</td>
<td>10%</td>
<td>28.3</td>
</tr>
<tr>
<td>Morbidly obese</td>
<td>4%</td>
<td>26.6</td>
</tr>
</tbody>
</table>
## SELECTING A TOTAL JOINT REPLACEMENT REGISTRY

FORCE-TJR QI brings comprehensive TJR registry outcomes (patient-reported measures, readmission and complications, and implant failures)

FORCE-TJR QI is a national leader in risk-adjusted outcome analyses and benchmarks.

Below is a checklist to help you (1) define your registry needs, (2) illustrate how specific functions can assist you, and (3) guide your questions when selecting a registry to meet your needs.

<table>
<thead>
<tr>
<th>Hospital/Surgeon needs</th>
<th>Required strategies/solutions</th>
<th>FORCE-TJR QI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Manage TJR utilization and outcomes to meet CJR and bundled payment goals.</td>
<td>Registry system follows the patient across time and locations, and is not linked to the hospital. Example: FORCE-TJR QI system is web-based and starts in the surgeon office captures data in the hospital, and for 12 months after TJR.</td>
<td>✔</td>
</tr>
<tr>
<td>a. Capture complete risk factors BEFORE surgery to guide patient pre-operative preparation and minimize risks.</td>
<td>Registry system returns data immediately in scored, trended format with national norms to support decisions. Example: FORCE-TJR QI Patient Risk Summary is generated real-time prior to surgery. It includes medical, emotional, and musculoskeletal risk factors, trended pain and function before surgery, and social needs.</td>
<td>✔</td>
</tr>
<tr>
<td>b. Capture pre-operative preparation steps, in-hospital events, and post-discharge monitoring to flag at-risk patients.</td>
<td>Registry system supports patient and clinician data entry, including process measures that address family, social supports, and in hospital needs. Example: FORCE-TJR QI coordinated care system integrates clinical observations and pre-operative risks to flag patients requiring close post-discharge follow-up.</td>
<td>✔</td>
</tr>
<tr>
<td>c. Capture &gt;70% of post-TJR outcomes at all locations</td>
<td>Registry system tracks and delivers PROs at 9-12 months after surgery and successfully captures more than 70%. Example: FORCE-TJR QI is the only registry in the US that has successful capture rates &gt;80% and offers training for hospitals and surgeons to replicate this rate.</td>
<td>✔</td>
</tr>
<tr>
<td>2. Provide risk-adjusted national benchmarks to guide quality improvement and anticipate public reporting.</td>
<td>Registry has statistical risk-adjustment models based on CMS that will display readmit rates to be publicly released. Example: FORCE-TJR QI has the most comprehensive risk-adjusted measures—no waiting to see public reports. In fact, CMS plans to adopt the additional FORCE risk factors.</td>
<td>✔</td>
</tr>
<tr>
<td>a. Risk-adjusted readmission rates</td>
<td>Registry provides norms and risk-adjusted PRO measures to guide care. Example: FORCE-TJR QI is the only US registry with risk-adjusted PRO measures!</td>
<td>✔</td>
</tr>
<tr>
<td>b. Risk-adjusted PRO measures</td>
<td>Registry has a statistical sample of US patients—not just a convenience sample—that represents the total US TJR population. Example: FORCE-TJR QI was funded to build national norms and is the only software that includes a sample of surgeons and patients that truly represents the US. Thus, benchmarks reflect true US practice.</td>
<td>✔</td>
</tr>
<tr>
<td>3. Collect data once and meet multiple goals and regulatory requirements.</td>
<td>Registry collects ALL CJR pilot measures and has national norms for benchmarking. (No additional data collection required). Example: FORCE-TJR informed what measures should be collected to allow for national norms and risk-adjustment.</td>
<td>✔</td>
</tr>
<tr>
<td>a. CJR and bundled payment metrics</td>
<td>Registry collects measures that will meet ALL PQRS expectations. Example: Our 16 QCDR approved measures are all PROs and include both process and outcome measures across 3 NQS Domains.</td>
<td>✔</td>
</tr>
<tr>
<td>b. PQRS incentives</td>
<td>Registry collects outcomes that will meet ALL ABOS maintenance of Certification expectations. Example: No additional work required FORCE-TJR QI collects and meets all ABOS.</td>
<td>✔</td>
</tr>
<tr>
<td>c. ABOS Maintenance of Certification</td>
<td>Registry collects all measures required for JCAHO Excellence. Example: FORCE-TJR QI collects PR functional status on pre-op patients</td>
<td>✔</td>
</tr>
</tbody>
</table>

Choosing the best TJR registry to meet your needs can be challenging. All registries are not alike; each has different data collection resources, reporting, and analytic capabilities.

Feel free to call us if we can assist you in understanding these criteria and selecting a TJR outcome registry.

1-855-993-6723

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Appendices

Appendix 1. FORCE-TJR Bibliography

PUBLICATIONS

1. Nguyen USDT, Ayers D, Li W, Harrold L, Franklin PD. Pre-operative Pain and Function: Profiles of Patients Selected for Total Knee Replacement. (Submitted)


30. Franklin PD, Allison JJ, Ayers DC. Beyond Implant Registries: A Patient-Centered Research Consortium For Comparative Effectiveness In Total Joint Replacement. JAMA. 2012(Sep); 308(12): 1217-8. PMID: 23011710
SELECT PRESENTATIONS: INTERNATIONAL and NATIONAL MEETINGS

(Website: www.force-tjr.org)

2016


3. Franklin PD. Understanding PRO (Patient Reported Outcomes). Orthopaedic Research Society (ORS) Session I Orlando, FL (March 2016) (invited lecture)


2015


10. Ware J, Gandek B, Franklin P, Lemay C. Cutting edge solutions to improving the efficiency of PRO measurement: from real-data simulations to pilot testing before and after total joint replacement in a national registry. International Society for Quality of Life Research (ISOQOL) Vancouver, BC (October 2015) (podium)


15. Franklin PD. Patient reported outcomes: Innovative approaches to bridging clinical practice and research. Academy Health Annual Research Meeting (ARM), MN (June 2015) (panelist)
2014


41. Ayers DC, Franklin PD. All Cause 30-Day Readmissions Rates Following Total Joint Replacement. Knee Society Charlotte, NC (October 2014) (paper presentation)


43. Franklin PD. Risk-adjustment for TJR: Lessons from cardiac surgery. Combined AOA/COA, Montreal Canada. (June 2014)

44. Franklin PD. Big data: FORCE-TJR and national data to inform TJR practice. Combined AOA/COA, Montreal Canada. (June 2014)


47. Franklin PD, Harrold L, Li W, Allison JJ, Lewis C, Ayers DC. Are all important predictors of pain and function after TKR and THR included in registry data? International Congress of Arthroplasty Registries, Boston, MA. (June 2014)


50. Franklin PD, Harrold L, Li W, O'Keefe R, Allison JJ, Ayers DC. Providing comprehensive, comparative post-TJR outcome feedback to surgeons for quality monitoring and value decisions. AcademyHealth Annual Research Meeting (ARM), San Diego, CA. (June 2014) (Poster)

51. Franklin PD. Activity measurement in TJR comparative effectiveness/outcomes research. UMCCTS (May 2014) (podium)


53. Lemay CA, Harrold L, Li W, Ayers DC, Franklin PD. Social support and total joint replacement: Differences preoperatively between patients living alone and those living with others. UMCCTS (May 2014) (poster)


55. Franklin PD, Ayers DC. Patient-reported outcomes in research. Orthopaedic Research Society, New Orleans, LA. (March 2014) (Panel)


57. Ayers DC, Harrold L, Li W, Allison JJ, Noble P, Franklin PD. Do younger TKR and THR patients have similar disability at time of surgery as older adults? Lessons From FORCE-TJR. Orthopaedic Research Society, New Orleans, LA. (March 2014) (Poster)

58. Franklin PD, Harrold L, Li W, Lewis C, Allison JJ. Important musculoskeletal predictors of patient-reported outcomes after TKR and THR are not included in risk models based on administrative data. Orthopaedic Research Society, New Orleans, LA. (March 2014) (Poster)

59. Franklin PD. Harrold L, Miozzari M, Hoffmeyer P, Ayers DC, Lubbeke A. Differences in patient characteristics prior to TKA and THA between Switzerland and the US. UMCCTS May 2014 and Orthopaedic Research Society, New Orleans, LA. (March 2014) (Panel)


63. Harrold L, Ayers DC, O'Keefe R, Lewis CG, Pellegrini V, Franklin PD. The validity of patient-reported short-
term complications following total hip and knee arthroplasty. UMCCTS May 2014 and American Academy of Orthopaedic Surgeons, New Orleans, LA. (March 2014) (Paper)


67. Ayers DC, Franklin PD. Risk-adjustment using clinical data when comparing clinical outcomes following TJR. American Association of Hip and Knee Surgeons, Dallas, TX. (November 2013) (Panel)


70. Franklin PD, Harrold L, Li W, Allison JJ, Ayers DC, Lewis C. Important predictors of patient-reported outcomes after TKR and THR are not included in risk models based on administrative data. ACR/ARHP American College of Rheumatology, San Diego, CA. (October 2013) (Poster)


2013


75. Harrold L, Ayers DC, Reed G, Franklin PD. Differences in functional gain between rheumatoid arthritis and osteoarthritis patients undergoing arthroplasty: Results from the FORCE-TJR national research consortium. Combined Meeting of Orthopaedics Societies, Venice, Italy. (October 2013) (Podium)

76. Harrold L, Li W, Allison JJ, Noble P, Ayers DC, Franklin PD. Do younger TKR patients have similar disability at time of surgery as older adults? Lessons from FORCE-TJR. Combined Meeting of Orthopaedics Societies, Venice, Italy. (October 2013) and UMCCTS (May 2014) (Poster)

77. Ayers DC, Harrold L, Li W, Allison JJ, Noble P, Franklin PD. Differences in pre-op characteristics between TKR and THR patients: results from FORCE-TJR a national us cohort. Combined Meeting of Orthopaedics Societies, Venice, Italy. (October 2013) (Podium)

79. Franklin PD, Harrold L, Miozzari H, Ayers DC, Lubbeke A. Differences in patient characteristics prior to TKA between Switzerland and the US. Annual meeting of the Swiss Society of Orthopaedic Surgeons and Traumatologists. Lausanne, Switzerland. (June 2013) (podium)

80. Franklin PD, Harrold L, Li W, Ayers DC. Has the level of disability at time of TKR changed over the past 10 years? Results from two US cohorts. International Congress of Arthroplasty Registries, Stratford-Upon-Avon, UK. (June 2013) (Podium)


83. Franklin PD, Harrold L, Ayers DC, Hoffmeyer P, Lubbeke A. Differences in patient characteristics prior to TKA between Switzerland and the US. International Congress of Arthroplasty Registries, Stratford-Upon-Avon, UK and European Federation of National Associations of Orthopaedics and Traumatology, Istanbul, Turkey. (June 2013) (Poster)

84. Lubbeke A, Miozzari H, Harrold L, Ayers DC, Franklin PD. Differences in patient characteristics prior to THA between Switzerland and the US. International Congress of Arthroplasty Registries, Stratford-Upon-Avon, UK and European Federation of National Associations of Orthopaedics and Traumatology, Istanbul, Turkey (June 2013) (Poster)


89. Ayers DC, Harrold L, Snyder B, Person S, Franklin PD. Clinical profile and disability levels of younger vs. older TKR and THR patients: results from a national research consortium. Orthopaedic Research Society, San Antonio, TX. (January 2013) (Poster)
Appendix 2. How FORCE-TJR Differs from other Registries

**Why is FORCE-TJR important to US patients, surgeons and policy makers?**

**Arthritis is a significant public health issue**

- 50 million U.S. adults diagnosed with osteoarthritis (OA)
- OA is leading cause of disability in US adults
- OA is #1 chronic condition among women and #2 most costly chronic condition in US
- Employer costs are >$9000 per OA employee

**Total joint replacement is common, costly, growing**

- More than 1,000,000 Total Hip and Knee Replacement surgeries each year
- Between 1997 and 2004, aggregate charges (the 'national bill') for primary TJR surgeries increased dramatically: from $8.9 billion to $50.5 billion (knees > hips).
- By 2030 the demand for THR and TKR is projected to grow by 174% and 673%, respectively
- Fastest growth among patients < 65 years of age

**Patients’ goals after TJR are pain relief and functional gain**

- TJR is a technically successful procedure
- Functional outcomes vary with both patient factors (e.g., gender, age, comorbidities) and health system delivery factors (e.g., hospital volume)

**Early registries primarily monitor revisions, while FORCE-TJR measures comprehensive quality and patient-reported outcomes.**

- Implant tracking TJR registries have existed for decades in Europe and Australia.
- US efforts have emerged to monitor implant revisions, including American Joint Replacement Registry and state-based registries (California, Michigan, Virginia).
- FORCE-TJR was designed to monitor comprehensive TJR outcomes including pain relief and functional gain (PROs), quality of care, and implant outcomes. All patients report pre-operative and post-operative PROs, 30 and 90 day post-operative events are monitored, and sub-optimally performing implants, both revised and not revised, are identified.
Appendix 3. FORCE-TJR Data Elements, Cohort Summary

FORCE-TJR data elements include:

<table>
<thead>
<tr>
<th>Data Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Attributes</strong></td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
</tr>
<tr>
<td><strong>Musculoskeletal comorbidities</strong></td>
</tr>
<tr>
<td><strong>Global Health</strong></td>
</tr>
<tr>
<td><strong>TJR Outcome</strong></td>
</tr>
<tr>
<td><strong>Implant/Surgery</strong></td>
</tr>
<tr>
<td><strong>Health System</strong></td>
</tr>
</tbody>
</table>

**FORCE-TJR Cohort**

FORCE-TJR patient sociodemographic and clinical profiles parallel national data (HCUP, CMS) demonstrating that the cohort is representative of US TJR patients. In addition, the first patient-reported normative data for before and after hip and knee replacement are now available.

The typical unilateral primary TKR patient is 66 years (45%<65 years), 63% female, mean BMI of 32, 33% with high school education or less, 39% with household income less than $45,000, 9% non-Caucasian, 24% with more than 2 medical comorbidities, and 29% with co-existing moderate-severe low back pain.

The typical unilateral primary THR patient is 64 years of age, 57% female, mean BMI of 29, 26% with high school education or less, 33% with household income less than $45,000, 7% non-Caucasian, 20% with more than 2 medical comorbidities, and 38% with co-existing moderate-severe low back pain.
Appendix 4. FORCE-TJR Methods/Data Quality

**Procedures and infrastructure for data collection:** FORCE-TJR built a centralized information technology system to automate timely distribution of PRO surveys via secure email with an individualized web link or mailed scannable paper, automated reminders, tracking for completion, and personal reminders, as needed, to assure complete follow-up. This flexibility in method of survey administration based on patient preference is practical with the direct-to-patient design.

**Cohort Design:** The FORCE-TJR cohort design optimized site and patient recruitment and retention to meet key goals:

- **Minimize patient and surgeon burden.**
  - User-friendly web-based and paper surveys to allow quick and complete data capture;
  - Primary outcomes from patients, validated clinically;
  - Follow-up data collection performed by FORCE-TJR staff.

- **Maximize participant retention.**
  - FORCE-TJR developed recruitment and retention methods to collect pre-TJR PROs on 96% of patients and post-TJR PROs on 85% of patients;
  - FORCE-TJR returned registry data to surgeons (surgeon-specific comparative outcome reports) encouraging active participation and supporting practice-level quality monitoring and improvement efforts in patient care.

- **Optimize data collection flexibility.**
  - Survey options meet patient and office needs;
  - Web-based data entry from home or office, supplemented with scannable paper surveys met all participant needs.

FORCE-TJR used direct-to-patient data collection supplemented with existing data obtained through either electronic data capture or manual chart review, depending on site capability. In both scenarios a standardized clinical review is performed to apply pre-defined standardized definitions and algorithms for each diagnoses. For example, the diagnosis of infection is not a code from the EMR. Clinic notes, labs, and treatment records are reviewed to assure standard definitions independent of the data were sent. The majority of the FORCE-TJR data are obtained from the patient, particularly through questionnaires summarizing pain and function. In addition, patients report key data including medical and musculoskeletal comorbidities. The ability to capture patient-centric outcomes over long-term follow-up is valuable for surgical procedures or implants since these are often intended to be long-lasting treatments. These patient-reported data are supplemented by electronic health record (EHR) information for patients who report post-operative adverse events and surgical data for all patients.
To assure complete data capture from community-based surgeon offices that comprise 75% of all cohort participants, the FORCE-TJR data coordinating center used a centralized telephone-based enrollment process.

Data were collected primarily from patients, supplemented by OR and clinical measures as needed. The following figure illustrates the type of data collected, the data source, and data collection timeframe.
Appendix 5:  FORCE-TJR Publications and Ancillary Studies Committee Procedures

FORCE-TJR welcomes scientific collaborations. The guidelines for research collaborations (publications, presentations and ancillary studies) are highlighted on the FORCE-TJR.org website.