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# A Bundle Protocol to Reduce the Incidence of Periprosthetic Joint Infections After Total Joint Arthroplasty: A Single-Center Experience

Matthew W. Bullock, DO, Matthew L. Brown, MD *, Daniel N. Bracey, MD, Maxwell K. Langfitt, MD, John S. Shields, MD, Jason E. Lang, MD

*Department of Orthopaedic Surgery, Wake Forest University Baptist Medical Center, Medical Center Boulevard, Winston-Salem, North Carolina*

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ABSTRACT

*Background:* Periprosthetic joint infection (PJI) represents a devastating complication of total hip arthroplasty (THA) or total knee arthroplasty (TKA). Modifiable patient risk factors as well as various intraoperative and postoperative variables have been associated with risk of PJI. In 2011, our institution formulated a "bundle" to optimize patient outcomes after THA and TKA. The purpose of this report is to describe the "bundle" protocol we implemented for primary THA and TKA patients and to analyze its impact on rates of PJI and readmission.

*Methods:* Our bundle protocol for primary THA and TKA patients is conceptually organized about 3 chronological periods of patient care: preoperative, intraoperative, and postoperative. The institutional total joint database and electronic medical record were reviewed to identify all primary THAs and TKAs performed in the 2 years before and following implementation of the bundle. Rates of PJI and readmission were then calculated.

*Results:* Thirteen of 908 (1.43%) TKAs performed before the bundle became infected compared to only 1 of 890 (0.11%) TKAs performed after bundle implementation ($P = .0016$). Ten of 641 (1.56%) THAs performed before the bundle became infected, which was not statistically different from the 4 of 675 (0.59%) THAs performed after the bundle that became infected ($P = .09$).

*Conclusion:* The bundle protocol we describe significantly reduced PJIs at our institution, which we attribute to patient selection, optimization of modifiable risk factors, and our perioperative protocol. We believe the bundle concept represents a systematic way to improve patient outcomes and increase value in total joint arthroplasty.



Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are successful operations that alleviate pain, restore function, and improve quality of life for patients with degenerative joint disease of the hip and knee. In 2010, the estimated annual incidence of primary THA and TKA in the United States was 293,000 and 655,000, respectively [1]. As our population ages and increasingly desires to remain physically active, utilization of total joint arthroplasty (TJA) is expected to increase exponentially. Projections estimate 572,000 THAs and 3.48 million TKAs will be performed annually in the United States by 2030 [1]. Periprosthetic joint infection (PJI) represents a devastating complication of TJA that is often associated with poor outcomes and significant patient morbidity. PJI after primary TJA has been reported to occur in 1.55%-2.5% of cases [2-4]. Hospital costs related to PJI were previously estimated at $566 million annually but are projected to rise to $1.6 billion by 2020 [2]. PJI is associated with higher mortality rates than several cancers, with a mortality rate of 7% between the first and second stages of a revision arthroplasty reported in one study [5].

Modifiable patient risk factors such as uncontrolled diabetes [6-13], obesity [8,14-16], tobacco abuse [8,17,18], malnutrition [18-25], alcohol abuse, poor dentition, anemia [9,26-28], and methicillin-resistant *Staphylococcus aureus* (MRSA) colonization [29,30] have been linked to increased risk of PJI after TJA. Prolonged operative time [3,7,29], extensive soft tissue dissection, presence of unnecessary personnel, disruption of intraoperative laminar

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* Reprint requests: Matthew L. Brown, MD, Department of Orthopaedic Surgery, Wake Forest University Baptist Medical Center, Medical Center Boulevard, Winston-Salem, NC 27157.

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airflow [31,32], and/or increased door openings in the operative suite may also contribute to PJI [32-34]. Correct timing and dosage of antibiotics [35], early patient mobilization, appropriate anticoagulation, adequate skin preparation, and using dedicated units for TJA patients [36] have been shown to reduce the risk of PJI. Hospital and surgeon volume are inversely related to PJI [37]. The impact each issue has on reducing infection has been examined individually but few studies have looked at combining interventions throughout the perioperative period.

Health care continues to transition to a patient-centered model where adverse patient outcomes, such as deep vein thrombosis (DVT)/pulmonary embolism (PE), readmission, or PJI may result in decreased reimbursement. Progressive research is necessary to help reduce the incidence and economic burden of PJI. The Institute for Healthcare Improvement developed the "bundle" concept aimed at improving healthcare delivery and enhancing outcome quality after medical interventions [38]. A bundle is a set of evidence-based guidelines that, when implemented together, yield improved results while minimizing cost.

In 2011, our institution conducted a comprehensive review of primary TJA cases, which led to creation of a multidisciplinary team focused on formulating a "bundle" to optimize patient outcomes. Our team included 3 fellowship-trained TJA surgeons, anesthesiologists, infectious disease specialists, nurses, physical therapists, and administrative coordinators. The purpose of this report is to describe the "bundle" protocol we implemented for primary TJA patients at our institution and to analyze its impact on rates of PJI and readmission.

## Materials and Methods

Our bundle protocol for primary TJA patients is conceptually organized about 3 chronological periods of patient care: preoperative, intraoperative, and postoperative (Table 1).

### *Preoperative Bundle*

The bundle begins during a patient's initial clinical visit. A checklist of 15 literature-supported patient-specific risk factors that influence the outcomes of TJA was assembled and implemented into our electronic medical record (EMR) system. Each arthroplasty surgeon completes the checklist during the initial evaluation of the patient (Table 2) to formulate a medical optimization plan and assign a level of infection risk before the operation. These factors include modifiable and nonmodifiable risk factors that have been shown to contribute to poor outcomes following TJA.

Modifiable risk factors include poor dentition [30,39,40], body mass index (BMI) >40 kg/m$^2$ [8,15,16,29,41], diabetes mellitus, hemoglobin A1c (HbA1c) [7,8,10-13,42,43], tobacco abuse [8,17,18,29], history of MRSA infection/colonization [44-46], history of or current open wounds, current use of anticoagulant, diagnosis of obstructive sleep apnea (OSA), and history of DVT/PE. Nonmodifiable risk factors include history of metal sensitivity/allergy, inflammatory arthritides (systemic lupus erythematosus, rheumatoid arthritis [47-51], psoriatic arthritis [47,51], ankylosing spondylitis) [47,51], previous TJA complication [52], and progressive neurologic disease.

Candidates with modifiable risk factors represent an opportunity for optimization before arthroplasty. Patients with poor dentition are referred to a dentist for evaluation and management. Obese patients with BMI >40 kg/m2 are referred to their primary care physician (PCP) and asked to work with a nutritionist to develop a weight management strategy before surgery. Occasionally, patients are referred to a bariatric surgeon for evaluation; however, evidence is mixed related to the impact of bariatric surgery improving outcomes after TJA [53-56]. Serum HbA1c is used to screen for diabetes mellitus. Patients with values greater than 7.0%

**Table 1**
Wake Forest Bundle Protocol by Operative Period.

| Preoperative | Intraoperative | Postoperative |
|---|---|---|
| Body mass index <40 kg/m$^2$ | Hair clipping in holding room | Dedicated total joint unit |
| Hemoglobin A1c <7.0% | Chlorhexidine wash | 24 h of antibiotics |
| Tobacco smoking <0.5 packs/day | Isopropyl alcohol wash | Standard wound care |
| Chlorhexidine wash instruction | Minimize OR traffic | Chlorhexidine wash |
| MRSA screen | Exchange gloves before implanting | Aspirin for low-risk patients |
| Risk factor labs | No "flashed" instruments | Follow-up instruction phone call |
| Preanesthesia appointment | Dilute povidone-iodine solution wash | |
| Surgeon risk factor assessment | Silver-impregnated dressing | |

OR, operating room; MRSA, methicillin-resistant Staphylococcus aureus.

**Table 2**
Surgeon Checklist Used During Initial Patient Evaluation As Part of Bundle Protocol.

| | |
|---|---|
| Surgeon risk factor assessment | |
| Surgical candidate based on examination and imaging | Yes/no |
| Patient factors to determine complication risk after TJA | |
| Poor dentition | Yes/no |
| History of metal intolerance | Yes/no |
| BMI (<40 kg/m$^2$) | Yes/no |
| Diabetes mellitus | Yes/no |
| Latest hemoglobin A1c (<7.0%) | Yes/no |
| Inflammatory arthritis (SLE, RA, psoriasis) | Yes/no |
| Gender | Male/female |
| Smoking | Yes/no |
| Prior skin infections or open wounds | Yes/no |
| Previous TJA complication | Yes/no |
| History or MRSA infection/colonization | Yes/no |
| History of progressive neurologic disease | Yes/no |
| Current anticoagulation use (coumadin, plavix, etc.) | Yes/no |
| History of obstructive sleep apnea | Yes/no |
| History of venous thromboembolism | Yes/no |
| Surgical risk of complications | Minimal/low/moderate/high |

TJA, total joint arthroplasty; BMI, body mass index; SLE, systemic lupus erythematosus; RA, rheumatoid arthritis; MRSA, methicillin-resistant Staphylococcus aureus.

**Table 3**
Prosthetic Joint Infection Incidence by Year Before and After Bundle Implementation.

| Fiscal Year | THA PJI | TKA PJI | Bundle Compliance | Readmission |
|---|---|---|---|---|
| 2012 | 2.22% (7/314) | 2.10% (8/380) | — | 15 (<30 d) |
| 2013 | 0.92% (3/327) | 0.95% (5/528) | — | 8 (<30 d) |
| Bundle starts | | | | |
| 2014 | 0.00% (0/300) | 0.19% (1/515) | 83.8% | 1 (<90 d) |
| 2015 | 1.06% (4/375) | 0.00% (0/375) | 92.5% | 3 (<30 d) |
| | | | | 1 (<90 d) |

THA, total hip arthroplasty; TKA, total knee arthroplasty; PJI, periprosthetic joint infection.

are referred to their PCP or an endocrinologist for improved glucose homeostasis.

Patients who smoke more than 0.5 packs per day are advised to reduce or quit before TJA because of impaired wound healing potential. These individuals are then referred to their PCP for smoking cessation interventions. Blood nicotine levels are monitored in high-risk patients. Patients with symptoms or a history of OSA are questioned regarding their compliance with continuous positive airway pressure therapy and/or referred for evaluation and treatment. OSA has been linked to increased hospital length of stay as well as perioperative gastrointestinal, renal, cardiopulmonary, and infectious complications [57]. Patients with a history of DVT/PE or those taking anticoagulants but who do not appear optimized are referred to a vascular specialist for evaluation and to determine a plan to minimize the risk of thromboembolic and/or hemorrhagic events after TJA. As such, we schedule regular clinic visits with these patients to monitor their progress and provide nonoperative modalities to manage joint pain until risk has been reduced.

Several weeks before surgery, patients meet with a provider from the preoperative anesthesia clinic to determine global operative risk and for preoperative blood work. Risk factor labs include complete blood count, basic metabolic panel, prealbumin/albumin, urinalysis with culture (in the presence of urinary symptoms), transferrin, HbA1c, and MRSA nasal swab. Laboratory abnormalities or an irregular test results in prompt intervention, which could include supplementation, PCP referral, or referral to a medical subspecialist for further medical optimization before surgery. MRSA carriers are instructed to apply mupirocin ointment intranasally twice daily for 5 days before surgery.

During the initial visit, patients are also introduced to the total joint navigator who works directly with each patient during their joint arthroplasty experience. In addition to home full-body chlorhexidine wash instructions for 3 days before surgery, each patient is provided with an informative folder detailing expectations, instructions, and appointment dates. Open communication is encouraged between the patient, surgeon, and total joint navigator with the aid of our electronic health record communication tool should questions arise.

*Intraoperative Bundle*

This section focuses on minimizing skin and wound contamination during TJA, as well as controlling the operating theater environment. The operating room is opened 1 hour before scheduled incision time to minimize equipment exposure to circulating microbes and room temperature is kept between 60°F and 65°F with relative humidity less than 60% [58]. All equipment is sterilized according to hospital protocol in compliance with Association for the Advancement of Medical Instrumentation requirements. Use of steam (flash) techniques to sterilize instruments is avoided for TJA cases due to recent concerns about sterilization parameters, contamination risks, and potential contributions to PJI [59-61]. Spare sterilized instrument trays are readily available in the operative suite if needed.

Surgical site depilation is completed in the holding area before transport to the operative suite. Electric clippers are used to remove hair instead of razors due to concerns over higher infection rates using the latter [62]. There is no current evidence that hair removal directly reduces PJI, but it seems to improve surgical site adhesive drape application, which may limit wound contamination. There is also some evidence to suggest that hair removal by any means (razor, depilatory, or clippers) is associated with increased risk of surgical site infection (SSI); however, these data do not come directly from patients undergoing TJA [63,64].

Patients with a history of MRSA receive weight-based (15 mg/kg) intravenous vancomycin in addition to weight-based intravenous cefazolin antibiotics (>60 kg = 2 g; >120 kg = 3 g) within 1 hour of incision. After the patient is positioned on the operating table, the entire extremity is prepared with a chlorhexadine sponge for 3 minutes followed by an isopropyl alcohol wash. Next, the operative site is prepped with an aqueous chlorhexadine/isopropyl alcohol (ChloraPrep, BD, Franklin Lakes, NJ) applicator. Lastly, the entire extremity is prepped with several iodine povacrylex (DuraPrep, 3M, St. Paul, MN) applicators. The practice of repeat surgical skin preparations significantly reduced SSI for TJA patients according to Morrison et al [65]. Tranexamic acid is administered to minimize blood loss.

Before incision, all nonvital staff clears the room while a surgical timeout ensures all necessary equipment, implants, and medications are in the room. This minimizes door opening during surgery, which disrupts airflow pressure gradients and increases circulating microbes during surgery [32,66,67]. The average primary arthroplasty case is under 2 hours. Surgical assistants, implant representatives, anesthesia personnel, and nursing staff have been thoroughly educated to remain in the room until the joint capsule is closed (iliotibial band for THA).

After the prosthesis is seated and the joint reduced, a dilute povidone-iodine mixture is poured into the wound and allowed to soak for 3 minutes which has been shown to help reduce PJI [68,69]. During this time, the skin around the incision is wiped with a povidone-iodine-soaked sponge before performing final wound irrigation with normal saline.

Meticulous closure of the joint capsule, subcutaneous tissues, and skin is emphasized to restore the body's natural layers against infection. The incision is sealed with a layer of cyanoacrylate adhesive (Dermabond, Ethicon, Somerville, NJ) [70,71] and finally covered with a silver-impregnated antibacterial dressing (Aquacel Ag, ConvaTec, Bridgewater, NJ) which has been shown to reduce incidence of acute PJI [72].

*Postoperative Bundle*

At our institution, arthroplasty patients are admitted to a separate floor isolated from other medical/surgical patients. Full-body chlorhexidine washes continue daily until hospital discharge to keep bacterial skin counts in check. Nursing staff inspects the surgical dressing daily and notifies the surgeon if more than 50% drainage is present on the dressing. Most arthroplasty patients are discharged on postoperative day 1 or 2.

Three to 5 days later, the clinic nursing staff conducts a post-discharge phone call to review instructions, answer questions, and provide treatment advice if indicated. The antibacterial dressing remains in place for 7 days.

*Records Review*

Institutional review board approval was obtained for this retrospective study. Current Procedural Terminology codes were used to search the EMR and billing database to identify hip and knee arthroplasty procedures performed from July 1, 2011, through December 31, 2015. Patients undergoing hip resurfacing, unicompartmental knee arthroplasty (UKA), hip hemiarthroplasty, simultaneous bilateral arthroplasty, or revision arthroplasty were excluded. Next, our medical records system cross-referenced the above group with hospital readmissions within 90 days of the index arthroplasty procedure. Manual chart review was undertaken for patients with PJI or readmission to verify the index arthroplasty procedure, identify patient comorbidities, determine reason(s) for readmission, and assess outcome measures. A PJI was defined

according to the Musculoskeletal Infection Society criteria and/or confirmed with positive culture results [73].

The total joint bundle protocol was implemented on July 1, 2013, by 5 faculty surgeons. Subjects who underwent TKA or THA before this date were assigned to the "pre-bundle" control group while patients who underwent TKA or THA after July 1, 2013, were included in the "post-bundle" group. To assess compliance with each step of the total joint bundle, 20 arthroplasty cases were randomly selected each month and thoroughly evaluated.

Categorical variables were compared between groups using chi-square analysis while continuous variables were compared using independent-sample Student *t* tests. An alpha value of 0.05 was used to determine statistical significance.

## Results

A total of 3114 primary TKA and THA procedures were performed at our institution during the study period (Table 3). During the 2 fiscal years before bundle implementation, 641 primary THAs were performed, 10 of which developed a PJI (infection rate, 1.56%). Of the 675 primary THAs performed during the 2 fiscal years following bundle implementation, 4 developed a PJI (infection rate, 0.59%). This 62% reduction of PJI rate for primary THA was not statistically significant ($P = .09$). There were 908 primary TKAs performed pre-bundle with 13 cases developing a PJI (infection rate, 1.43%). Post-bundle, 890 primary TKAs were performed and only 1 developed a PJI (infection rate, 0.11%). This 92.3% reduction in PJI rate for TKA after initiation of the bundle was statistically significant ($P = .0016$). In total, 28 PJIs were identified: 26 were discovered within 30 days of the index procedure while the remaining 2 PJI cases were discovered by 90 days.

By the end of the post-bundle period of study, the average overall compliance with each step of the total joint bundle was 88%. Trend analysis demonstrated compliance normalized with time.

## Discussion

A total joint bundle was implemented at our institution to reduce PJI after primary TKA and THA. The total joint bundle included evidence-based practices to guide patient care during the perioperative period. Over a 2-year period, we have seen a significant reduction in the incidence of PJI following primary TKA and a trend toward decreased PJI following primary THA.

The concept of a joint bundle has previously been described in the arthroplasty literature. In a large multicenter study, Schweizer et al [74] employed a bundled intervention to decrease *Staphylococcus aureus* (SA) SSI in patients undergoing cardiac and joint arthroplasty procedures. Their bundle consisted of screening for SA carriers and prophylactically treating them with intranasal mupirocin and surgical site chlorhexidine washes for 5 days before surgery. Vancomycin and a cephalosporin were used for perioperative antibiotic prophylaxis. Eight hospitals adopted the bundle for 11,000 TJA patients. They reported a significant reduction in the rate of complex SA SSI following THA and TKA (difference per 10,000 operations, −17). Interestingly, rates of SSI decreased significantly for scheduled elective operations but did not decrease after urgent or emergent cases, consistent with our belief that modifiable risk factors should be addressed before elective cases.

Matsen Ko et al [75] decreased their incidence of partial, primary, and revision PJI from 1.7%-0.4% at a community hospital. Specifically, primary TKA and THA PJI dropped from 1.4%-0.37% over a 5-year period. PJI surveillance was 12 months in their study compared to 90 days in our study. Their interventions paralleled our total joint protocol through staff education, preoperative patient optimization, proper dose and timing of antibiotics, surgical site skin preparation, DVT prophylaxis, and dilute povidone-iodine wound irrigation.

Gottschalk et al [76] devised an evidence-based protocol to decrease PJI in a high-risk immunocompromised indigent patient population. The authors reviewed outcomes following TJA in 178 patients undergoing primary and revision TJA and each patient had a minimum 2-year follow-up. The PJI rate decreased from 12.9% before the bundle to 1.9% after bundle implementation. Similar to our optimization, they limited patients to a BMI <36 kg/m$^2$, nonsmokers, and with HbA1c <6.5%. In addition to limiting operating room traffic, frequent glove exchanges, standard anticoagulation, and consistent postoperative dressings, they used consultation of medical specialists (internal medicine, infectious disease) and/or allied health professionals (dietitians, social work, dentistry) to optimize patients before surgery.

Fornwalt et al [36] reported on a series of quality improvement modifications combined with surface contamination control in operating rooms with pulsed ultraviolet light to lower their number of PJIs from 7 of 544 primary TJAs (1.29%) to 0 of 585 primary TJAs (0%) over a 12-month period at a single community hospital. Preoperative patient education sessions combined with MRSA screening and decolonization, chlorhexidine baths, and early postoperative mobilization were central to the quality improvement arm of their protocol. They reported a significant reduction in PJI for THA but not for TKA. Given the small number of PJIs, they were unable to determine the effects of the individual arms of their protocol.

Our results demonstrate that the total joint bundle protocol significantly reduced the incidence of PJI for primary TKA but not for primary THA. One possibility is that we are only seeing a trend toward significance because our THA group is underpowered. We would require an additional 1300 patients in the post-bundle THA group to achieve statistical significance, assuming our infection rate remains constant. An alternative, and more intriguing, possibility is that our bundle is more effective in preventing PJI after TKA compared to THA.

Interestingly, Watts et al [77] reported that subcutaneous fat thickness was strongly associated with complications, including reoperation and infection, following TKA. We believe this finding may help to explain our bundle's preferential impact on reducing PJI in TKA compared to THA. THA patients may already be at slightly elevated risk of infection over TKA merely due to depth of subcutaneous dissection, which is usually greater for the hip compared to the knee. Additionally, the hip region, besides being in closer proximity to the end of the digestive tract, experiences more perspiration than the knee due to the presence of clothing, potentially increasing risk of infection. Our bundle does not seem to include interventions that plausibly modify these conditions.

Of the 28 infected primary TJA patients, 2 common patient risk factors were frequently observed: obesity (>40 kg/m$^2$) and history of tobacco use (current or former). Due to the low incidence of infection, we are unable to perform regression analysis on these factors.

By the end of our study, we had 88% average compliance with our total joint bundle. Some deviation exists during medical optimization before surgery, and some surgeons are more accepting of slightly higher BMI, tobacco use, or HbA1c. Schweizer et al [74] suggested bundle adherence decreased their infection rates. They reported an overall 83% bundle compliance rate based on 5 randomly selected cases per month. In 2015, our compliance rate improved to 92.5% but overall TJA infection rate slightly increased. We expect this variation to normalize as more data are collected. We have now instituted methods to track all aspects of compliance for each and every patient.

Hip hemiarthroplasty, THA after trauma, and UKA data were excluded from our analysis. Partial hip arthroplasty or THA for the management of hip fractures represents a subpopulation of patients who usually present with other comorbidities that typically cannot be optimized before surgery given the nonelective nature of these injuries. Second, infection rates for UKA are historically lower than TKA. This may be due in part to smaller exposure, less dissection, and shorter operating times. Intraoperative dilute povidone-iodine irrigation is not used during hip hemiarthroplasty and UKA due to concerns of possible chondrocyte toxicity [78].

While the total joint bundle elements described above are applied to revision TKA and THA, these cases were also excluded from analysis because of increased risk of PJI due to prior surgery, existing hardware, longer operating times, larger dissection, increased blood loss, and more equipment and personnel occupying the operating suite. Although not the focus of this article, revision arthroplasty cases demonstrated a trend of lower PJI rates when bundle parameters were followed.

### *Limitations*

Identifying PJIs was difficult and required multiple revisions of our search algorithm within the limitations of our retrospective study design. Before our EMR system, documentation of a PJI was inconsistently reported among providers and recorded in several different mediums. As part of a hospital's infection rate and overall care quality, all PJIs are reported to proper governing bodies. Frequently, these reports fail to distinguish between those PJI that are referred from an outside facility and those as a result of the index procedure performed at our institution. Some patients may have had their PJI managed at another facility without our knowledge. Today, hospitals have the potential to securely share patient information with integrated EMR systems, thus helping to promote enhanced continuity of care. Our PJI data are now regularly updated and frequently shared among teams to give accurate feedback and promote continued ideas for future infection control interventions.

According to Parvizi et al [79], culture-negative PJIs may occur up to 50% of the time. For our study, PJI were identified by Musculoskeletal Infection Society criteria [80], which does not require a positive intraoperative culture. With inefficient methods to accurately capture and diagnose infections, we are unable to state how many PJIs were not identified during our study. Promising new research suggests synovial fluid biomarkers may hold the key to more accurately diagnosing a PJI [81-83].

Another limitation of our study is the 90-day period used to identify PJI, although this time interval has been used by other studies. Ninety days after the index arthroplasty procedure is the proposed time frame for the insurance bundled payment system where complications such as PJI will not be reimbursed or result in penalty. Our data demonstrate the overwhelming majority of the PJIs occurred within 30 days of the index procedure, but long-term surveillance is needed to define late infection trends.

Lastly, surgeon turnover during the study period represents a potential confounding factor. During our study period, one arthroplasty surgeon left the institution while 2 new fellowship-trained arthroplasty surgeons were hired. The total joint bundle has helped to standardize expectations for all staff.

## Conclusion

Since implementation of the total joint bundle protocol, we have witnessed a significant reduction in the incidence of PJIs at our institution. This can be attributed to careful patient selection and optimization of modifiable risk factors in addition to the steps implemented in our perioperative protocol. We believe the evidenced-based total joint bundle can significantly reduce rates of PJI and therefore decrease patient morbidity and healthcare expense associated with TJA. Stronger relationships have been formed between our surgeons, the anesthesia team, medical subspecialists, and family physicians to better manage the whole patient and not just their affected extremity. Future endeavors are directed toward cost-benefit analysis and investigating high-risk PJI patients. The bundle is more than a checklist—it represents an evolving cultural transformation regarding the approach to TJA at our institution.

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