



WHITE PAPER

**GENERATING CLINICALLY USEFUL
REAL-WORLD EVIDENCE
FOR TKA AND THA WITHIN
A CLOSED DATA SYSTEM**

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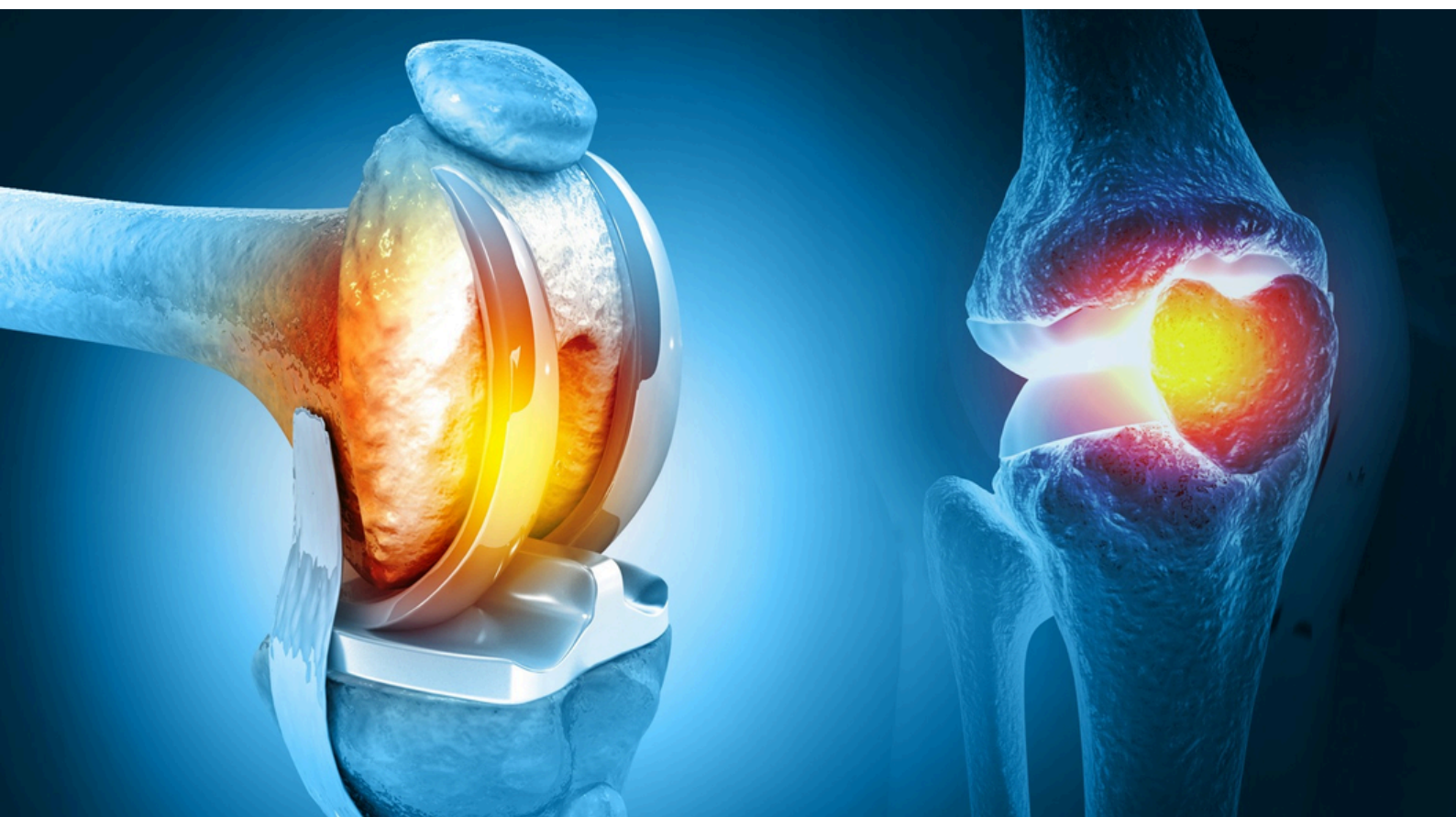


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This report provides a comprehensive analysis of the framework, generation, and utilization of clinically useful Real-World Evidence (RWE) for Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA), derived exclusively from data collected and validated within a proprietary closed data system. It deliberately excludes reliance on external data sources like general Electronic Health Records (EHRs) or insurance claims, where primary source data validation presents significant challenges. The purpose is to guide organizations utilizing such closed systems in maximizing their value for internal clinical quality improvement and patient care optimization.

The analysis defines RWE within this specific context, emphasizing the shift from broad generalizability towards high internal validity achieved through controlled data collection and validation processes. Key findings identify the crucial types of data reliably collectable: detailed clinician/staff entries (surgical techniques, implant specifics, observed complications), patient-reported data captured directly via integrated system tools (notably Patient-Reported Outcome Measures - PROMs), and potentially data from validated, integrated medical devices or diagnostics. Clinically useful data points include specific PROMs (e.g., KOOS JR, HOOS JR, PROMIS), precise implant identifiers including lot numbers, granular surgical technique details, system-documented complications, functional metrics like range of motion (ROM) or validated wearable data, and essential patient demographics and comorbidities entered directly.

The report details how this internally generated RWE can be powerfully leveraged for internal quality benchmarking (comparing surgeons, techniques, implants used within the system), driving comparative effectiveness research relevant to the system's user base, tracking longitudinal patient progress with high fidelity, and informing the refinement of local care pathways and protocols. Optimal methods for collecting high-quality PROMs directly from patients using the system's interfaces (e.g., integrated surveys via patient portals, clinic-based tablets) are evaluated, alongside strategies for maximizing patient engagement. Rigorous data quality assurance protocols, including standardized data dictionaries, automated validation rules, and internal auditing, are presented as critical for maintaining the trustworthiness of the RWE generated.

Challenges related to sustaining long-term patient engagement for data collection, data curation, and system maintenance are discussed. Finally, the potential application of advanced analytics, including Artificial Intelligence and Machine Learning (AI/ML), on the validated internal data is explored, highlighting opportunities for developing predictive models, identifying subtle outcome patterns, and personalizing care pathways specifically for the patient population served by the system.

Key recommendations emphasize prioritizing the collection of granular, validated data; establishing robust data quality assurance mechanisms from inception; investing in user-friendly PROM collection strategies; actively utilizing the generated RWE for internal improvement cycles; cautiously exploring AI/ML for locally relevant insights; transparently acknowledging limitations; and ensuring sustained organizational commitment to maintain the system's integrity and value over the long term.

The concept of Real-World Evidence (RWE) has gained significant traction in healthcare, driven by the increasing availability of routinely collected health data and regulatory initiatives like the 21st Century Cures Act.¹ Understanding its definition and application is crucial, particularly when considering its generation within the unique confines of a proprietary closed data system for orthopedic procedures like Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA).

Adapting Standard RWE Definitions for Internal Validity

Regulatory bodies like the U.S. Food and Drug Administration (FDA) define Real-World Data (RWD) as "data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources".² These sources commonly include EHRs, medical claims and billing data, product and disease registries, and patient-generated health data, including from digital health technologies.² RWE, consequently, is defined as "the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD".³ This evidence is increasingly used to inform regulatory decisions, potentially supporting new drug or device indications, augmenting understanding of safety profiles, or fulfilling post-approval study requirements.² The ultimate goal often involves integrating RWE into regulatory submissions to enhance the efficiency of clinical research and decision-making.⁸

However, when applying these definitions to a proprietary *closed* data system for TKA/THA, a critical distinction emerges. The "variety of sources" for RWD is intentionally limited. Instead of drawing from disparate external systems like general EHRs or broad claims databases – sources where data provenance, consistency, and validation back to the primary clinical event can be difficult or impossible for the system owner to ascertain⁶ – a closed system relies exclusively on data streams generated and validated *internally*.

These typically include data entered directly by clinicians and staff involved in the patient's care within the system, information reported directly by patients through integrated tools, and potentially data fed directly from connected medical devices or diagnostic instruments that have been specifically validated and integrated into the system's architecture.

Therefore, while the fundamental definition of RWE as evidence derived from RWD analysis³ remains constant, its practical character undergoes a significant transformation within a closed system. The emphasis naturally shifts from the broad external generalizability often pursued for regulatory purposes or large population health studies⁵ towards achieving high internal validity and direct relevance to the specific patient population and clinical practices encompassed by the system.

Standard RWE approaches frequently involve aggregating large, heterogeneous datasets, accepting potential variations in data quality and completeness as a trade-off for capturing a wide breadth of experience.⁷



In contrast, a closed system prioritizes control, standardization, and validation over sheer breadth, fundamentally altering the resulting evidence's strengths and limitations. The primary objective may not solely be external regulatory submission (though this remains a possibility for specific devices or therapies used and tracked within the system), but rather the generation of trustworthy evidence to drive internal quality improvement, optimize local protocols, and deepen understanding of treatment effectiveness within its specific operational context.

The Value Proposition of Internally Generated and Validated Data

The deliberate constraint of sourcing data internally within a closed system offers significant advantages, primarily centered around data quality and trustworthiness. RWD sourced from external, general-purpose systems like EHRs or claims databases often suffers from inherent limitations when repurposed for research or evidence generation.

These limitations include variability in data recording practices across different institutions or providers, significant issues with data completeness (missing fields or entire encounters), lack of standardized definitions for clinical events or variables, and potential inaccuracies or biases stemming from their original administrative or billing purposes.¹ Consequently, substantial effort is often required for data cleaning, harmonization, and making assumptions to render such external data usable for analysis, potentially introducing further uncertainty.¹¹

A proprietary closed system, conversely, provides the opportunity to proactively manage the data lifecycle. It allows for the establishment and enforcement of specific data standards, detailed collection protocols, and rigorous validation rules *at the point of data entry*. Clinicians, staff, and patients interact with system interfaces designed with data quality in mind. This can involve structured data entry forms, mandatory fields for critical information, predefined picklists using standardized terminology, and automated checks for logical consistency or plausible values. As a result, the RWD collected within the closed system has the potential to be significantly more complete, accurate, consistent, and reliable compared to externally sourced data.¹

This enhanced data integrity directly translates into RWD that is more readily "fit-for-purpose" for addressing specific clinical questions relevant to the system's users.¹ The primary value proposition, therefore, becomes the generation of *trusted* evidence for internal decision-making. By controlling the data from its inception through collection, storage, and analysis, the system can produce RWE that clinicians, surgeons, and administrators within that specific healthcare ecosystem are more likely to accept as valid and actionable.

This heightened confidence is crucial for driving meaningful quality improvement initiatives, such as internal benchmarking, evaluating the effectiveness of specific surgical techniques or implants used locally, and refining perioperative care pathways based on observed outcomes within their own patient population. The path from data collection to actionable evidence becomes more direct and less encumbered by the extensive cleaning and validation challenges associated with external RWD sources, fostering a stronger foundation for data-driven clinical practice improvement within the confines of the system.

DATA CAPTURE WITHIN THE PROPRIETARY SYSTEM: SOURCES AND VALIDATION

A well-designed proprietary closed system for TKA/THA leverages multiple internal streams to capture high-quality RWD. The reliability of the resulting RWE hinges on the system's ability to collect comprehensive data from these sources and validate its accuracy and completeness within its own controlled environment. The key sources are clinician/staff entries, direct patient reports, and integrated device/diagnostic data.

Clinician and Staff-Entered Data: Capturing Surgical Nuances and Observations

Data entered directly by surgeons, nurses, anesthesiologists, and other clinical staff at the point of care forms a cornerstone of the RWD within a closed system. This allows for the capture of granular details often missing or inconsistently recorded in external administrative datasets or even some registries.¹²

Key data types include:

- **Precise Surgical Technique Details:** Information beyond simple procedure codes, such as the specific surgical approach employed (e.g., anterior, posterior, lateral for THA; medial parapatellar, midvastus, subvastus for TKA)¹³, method of implant fixation (cemented, cementless, hybrid)¹³, details on bone preparation, specific alignment targets and achieved results (if measured intraoperatively and recorded), use of enabling technologies like computer navigation or robotic assistance¹⁴, type of anesthesia administered (e.g., general, spinal, regional blocks)¹⁴, and potentially specific soft tissue balancing techniques or ligament releases performed.

- **Specific Implant Identifiers:** Crucially, this includes not just the manufacturer, model name, and size of each implanted component, but also the unique *lot numbers* or serial numbers.¹⁴ This level of detail is essential for precise implant surveillance and tracking within the system.
- **Intra-operative Metrics:** Data recorded during the procedure, such as operative duration (e.g., surgery-controlled time, anesthesia-controlled time)¹⁷, estimated blood loss, use of specific instruments or adjuncts (e.g., tranexamic acid, bone graft material¹⁴), and any intra-operative complications observed directly.¹⁴
- **Directly Observed Complications:** Recording of adverse events noted during the surgery or during the inpatient stay managed within the system's purview (e.g., intraoperative fracture, nerve injury, immediate post-operative wound issues, dislocation, signs of early infection documented before discharge).¹³
- **Relevant Patient Factors:** Baseline information confirmed and entered at the point-of-care, such as American Society of Anesthesiologists (ASA) physical status classification¹⁴, Body Mass Index (BMI)¹⁴, primary diagnosis leading to arthroplasty (e.g., osteoarthritis, inflammatory arthritis)¹⁴, and key comorbidities identified as relevant during pre-operative consultations or assessments (e.g., diabetes, cardiovascular disease, smoking status).

To maximize consistency and quality, the system interface should utilize structured data entry forms with clear definitions, standardized terminologies (where applicable), and constrained input options (e.g., picklists, checkboxes) rather than relying heavily on free text. Validation mechanisms embedded within the system are crucial. These can include automated checks for data completeness (ensuring mandatory fields are filled), range checks (e.g., ensuring BMI is within a plausible range), logical consistency checks (e.g., verifying that components selected are compatible), and potentially audit trails to track data entry and modifications.

Patient-Reported Data: Leveraging Integrated System Tools for Direct Input (PROMs)

Capturing the patient's perspective on their symptoms, function, and quality of life is essential for evaluating the true success of TKA and THA.²² Patient-Reported Outcome Measures (PROMs) are the standard tool for this. A closed system offers the significant advantage of collecting PROM data *directly* from patients via integrated tools, bypassing the need for manual transcription from paper forms or data pulls from separate, external survey platforms. This direct digital capture enhances efficiency and reduces potential transcription errors. Key data types include:

- **Validated PROM Instruments:** Standardized questionnaires assessing pain, function, stiffness, and overall health status. Commonly used and validated instruments for TKA/THA include:



- *Condition-Specific:* Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR)²², Hip disability and Osteoarthritis Outcome Score for Joint Replacement (HOOS JR)²², Oxford Knee Score (OKS) / Oxford Hip Score (OHS)²², Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).²⁵
- *Generic Health Status:* Patient-Reported Outcomes Measurement Information System (PROMIS) tools (e.g., PROMIS Global Health [Physical and Mental], PROMIS Pain Interference, PROMIS Physical Function - often available as short forms or Computerized Adaptive Tests (CATs))²², EuroQol 5-Dimension (EQ-5D)²², VR-12 or SF-12.²⁵
- **Patient Satisfaction and Expectations:** Direct questions regarding satisfaction with the surgical outcome and whether the procedure met their pre-operative expectations.¹⁴
- **Patient-Entered Baseline Data:** Information provided directly by the patient through system interfaces, potentially including demographics, relevant medical history (beyond clinician entry), social determinants of health (SDOH) factors if collected using validated questionnaires integrated into the system (e.g., questions about employment, living situation, health literacy⁶), and pain/function relating to contralateral or other joints.²⁸

Collection should occur at standardized time points: a baseline assessment pre-operatively (ideally within 90 days of surgery²⁶) and at multiple post-operative intervals (e.g., 6 weeks, 3 months, 6 months, 1 year, and potentially longer for longitudinal tracking²⁷). The system's integrated tools (e.g., secure patient portal, clinic-based tablets, dedicated mobile app) facilitate this direct capture.²⁴ Validation focuses on ensuring survey completion, potentially checking for highly inconsistent response patterns within a single survey (though challenging with subjective measures), time-stamping entries accurately, and ensuring secure patient authentication to link responses correctly to the individual.

Integrated Device and Diagnostic Data: Potential and Prerequisites for Inclusion

The RWD within a closed system can potentially be enriched by data flowing directly from integrated medical devices or diagnostic tools, offering objective measures to complement clinician and patient reports. However, the "closed system" principle imposes strict requirements for including such data:

- **Validated and Integrated Devices:** Data should only be incorporated from devices that have been specifically *validated* for clinical accuracy and relevance *and* technically *integrated* to feed data directly and reliably into the proprietary system. Examples might include:



- *Wearable Sensors:* Specific, validated sensors providing metrics like daily step counts, cadence, objective range of motion measurements, or time spent in different activity levels.³⁰ The validation must confirm that the sensor accurately measures the intended parameter and that the parameter itself has clinical meaning in the context of TKA/THA recovery. Simple consumer-grade fitness trackers without specific validation and integration would typically not meet this standard within a rigorously controlled closed system.³⁴
- *Diagnostic Tools:* Quantifiable parameters derived from imaging modalities (e.g., specific alignment angles measured from radiographs using a validated tool integrated with the system's PACS) or other diagnostic equipment directly interfaced with the system.
- *Intra-operative Sensors:* Data from specialized intra-operative tools, such as sensors used for assessing ligament balance or implant stability during TKA¹⁶, could be included if the system is explicitly designed to capture, store, validate, and analyze these specific data points for defined clinical endpoints (e.g., correlating sensor readings with post-operative PROMs or stability). If the sensor is merely used as a surgical aid without structured data capture and validation within the system, its readings would not constitute reliable RWD for RWE generation.
- **Crucial Caveat on Validation:** The defining characteristic is rigorous validation *within the context of the closed system's intended use*. This involves technical validation (ensuring accurate and secure data transmission from the device to the system), analytical validation (confirming the device measures what it purports to measure reliably), and clinical validation (demonstrating that the measured parameter correlates with meaningful clinical outcomes or patient status). Raw, uninterpreted data streams (e.g., raw accelerometer data) without validated algorithms transforming them into clinically meaningful metrics would generally be excluded.

The integration of device data requires careful planning and execution. Unlike broader RWE initiatives that might attempt to aggregate data from a wide array of consumer devices with varying quality⁶, a closed system necessitates a deliberate approach. This might involve partnerships with specific device manufacturers whose products meet the required validation standards or the development of internal protocols for validating and integrating selected devices. The goal is to ensure that any device data incorporated maintains the overall high standard of data quality and reliability that is the hallmark of a well-managed closed system. Failure to enforce these standards would dilute the system's core advantage of data trustworthiness.

PROPOSED TABLE 1: VERIFIABLE DATA SOURCES AND TYPES WITHIN THE CLOSED SYSTEM

Data Source Category	Specific Data Type	Collection Method within System	Key Validation Considerations
Clinician/Staff Entered	Surgical Approach (e.g., THA Anterior)	Structured Surgical Form (Picklist)	Defined list of approaches, Mandatory field
	Implant Component Lot Number	Structured Surgical Form (Text/Barcode Scan)	Format check, Uniqueness check (if possible), Mandatory field
	Implant Fixation Method (e.g., Cementless Femur)	Structured Surgical Form (Checkboxes/Picklist)	Mutually exclusive options, Consistency check with components
	Intra-operative Complication (e.g., Periprosthetic Fracture)	Structured Surgical Form (Picklist + Optional Text)	Standardized complication list, Completeness check for details
	Anesthesia Type (e.g., Spinal + Sedation)	Anesthesia Record Interface/Structured Form	Standardized list, Consistency with other records
	ASA Physical Status Classification	Pre-op Assessment Form (Picklist)	Standardized scale (I-VI), Mandatory field
	Body Mass Index (BMI)	Pre-op Assessment/Intake Form (Calculated/Entered)	Range check (e.g., 15-60), Calculation accuracy if automated



PROPOSED TABLE 1: VERIFIABLE DATA SOURCES AND TYPES WITHIN THE CLOSED SYSTEM

Data Source Category	Specific Data Type	Collection Method within System	Key Validation Considerations
	Discharge Disposition	Discharge Summary Form (Picklist)	Standardized options (Home, Rehab, SNF), Mandatory field
Patient Reported	KOOS JR / HOOS JR Score	Integrated PROM Survey (Portal, Tablet, App)	Secure patient authentication, Completion check, Time-stamping, Validated instrument use
	PROMIS Global Health Score	Integrated PROM Survey (Portal, Tablet, App)	Secure patient authentication, Completion check, Time-stamping, Validated instrument use
	Patient Satisfaction Score (e.g., 1-5 scale)	Integrated Post-op Survey (Portal, Tablet, App)	Secure patient authentication, Completion check, Clear anchor definitions
	Health Literacy Proxy (e.g., SILS-2)	Integrated Pre-op Survey (Portal, Tablet, App)	Secure patient authentication, Completion check, Validated question use



PROPOSED TABLE 1: VERIFIABLE DATA SOURCES AND TYPES WITHIN THE CLOSED SYSTEM

Data Source Category	Specific Data Type	Collection Method within System	Key Validation Considerations
	Contralateral Joint Pain	Integrated Pre-op Survey (Portal, Tablet, App)	Secure patient authentication, Completion check, Standardized scale
Integrated Device/Tool	Validated Sensor: Daily Step Count	Direct Feed from Validated/Integrated Wearable API	Sensor calibration/accuracy validation, Secure data transmission protocol, Data mapping to patient
	Validated Sensor: Objective ROM	Direct Feed from Validated/Integrated Wearable API	Sensor validation for ROM accuracy, Secure data transmission, Data mapping to patient
	Clinician-Entered ROM	Post-op Follow-up Form (Numeric Entry)	Range check (e.g., Knee Flexion 0-150 deg), Unit consistency (degrees)
	Validated Imaging Parameter (e.g., Cup Inclination)	Direct Feed/Entry from Integrated/Validated PACS Tool	Tool validation for measurement accuracy, Standardized measurement protocol, Data mapping



While a closed system *can* capture a vast amount of data, its practical value lies in collecting the *right* data – those elements that are clinically actionable and directly support internal quality improvement, patient care, and research objectives. Prioritization is essential to balance comprehensiveness with the feasibility of collection and the burden on clinicians and patients.¹¹ The following categories represent key data points for TKA/THA RWE generation within a proprietary closed system:

Core Patient-Reported Outcome Measures (PROMs): Assessing Pain, Function, and Satisfaction

As TKA and THA primarily aim to alleviate pain and improve function and quality of life, PROMs are arguably the most critical outcome data.¹⁵ Collection should focus on:

- **Validated Instruments:** Prioritize widely accepted, psychometrically sound measures. For condition-specific assessment, KOOS JR (for TKA) and HOOS JR (for THA) are frequently used and mandated for some reporting programs.²² Other strong options include the Oxford Knee Score (OKS) and Oxford Hip Score (OHS).²²
- **Generic Health Status:** Complement condition-specific measures with generic instruments to capture overall health perception. PROMIS measures (e.g., Global Health, Physical Function, Pain Interference) offer robust options, often with efficient short forms or CAT versions.²² Other choices include the VR-12/SF-12 or EQ-5D.²³
- **Satisfaction and Expectations:** Include simple, direct questions assessing overall patient satisfaction with the procedure and whether their pre-operative expectations were met.¹⁴
- **Collection Timing:** Implement a standardized schedule. A baseline measurement pre-operatively (e.g., within 90 days before surgery²⁶) is essential. Post-operative collection should occur at key recovery milestones. While CMS mandates focus on a ~1-year post-op window (270-365 days) for certain programs²⁴, a proprietary system can capture data more frequently (e.g., 6 weeks, 3 months, 6 months, 1 year, 2 years, 5 years) to understand the full recovery trajectory and long-term outcomes, although long-term follow-up presents engagement challenges.²⁷

Essential Surgical and Implant Details: Ensuring Traceability and Technique Analysis

The ability to link specific surgical actions and implants to patient outcomes is a key strength of a well-designed closed system.¹² Mandatory capture should include:



- **Unique Implant Identification:** Capture manufacturer, model name/number, size, and critically, the *lot number or serial number* for every implanted component (femoral, tibial, patellar, acetabular cup, liner, head).¹⁴ This level of granularity is vital for internal surveillance, identifying potential batch issues rapidly, and conducting precise comparative effectiveness analyses between implants used within the system.¹⁵
- **Key Surgical Technique Variables:** Document core aspects of the procedure consistently. This includes the surgical approach used¹³, the method of fixation for each component¹³, whether navigation, robotics, or specific intra-operative sensors were employed¹⁴, details on bone graft usage¹⁴, and the type of anesthesia administered.¹⁴ Depending on the system's goals, more granular details like specific alignment parameters achieved or soft tissue balancing steps could also be mandated.

This detailed linkage, often difficult to achieve reliably with external RWD sources that may lack surgical granularity or consistent implant identifiers¹², allows the system to perform nuanced analyses of how specific surgical choices impact outcomes within its specific user and patient context.

Documenting Complications: Intra-operative and Post-operative Events Captured Systemically

Tracking adverse events is crucial for patient safety and quality assessment. The closed system should facilitate standardized documentation of:

- **Intra-operative Complications:** Events occurring during the surgery itself, such as iatrogenic fracture, significant nerve or vessel injury, or excessive bleeding, should be recorded using standardized definitions or picklists within the operative record module.¹⁴
- **Post-operative Complications (within system purview):** Adverse events identified during the inpatient stay or at follow-up visits managed within the system. This includes surgical site infections (superficial or deep/periprosthetic joint infection - PJI), wound healing problems (dehiscence, persistent drainage), venous thromboembolism (DVT/PE) diagnosed internally, dislocation (for THA), nerve palsies noted post-operatively, and significant medical complications (e.g., acute kidney injury, delirium).¹⁴ It is important to recognize that complications treated entirely outside the system's network or purview might be missed, representing a limitation.
- **Reoperations and Revisions:** Clear documentation of any subsequent surgical procedures on the index joint performed within the system, including the reason for reoperation/revision (e.g., infection, instability, aseptic loosening, fracture) and the type of procedure performed.¹³ Some registries differentiate between reoperations (minor procedures not involving component exchange) and revisions (involving exchange, removal, or addition of components).¹³



Consistent definitions and systematic capture are key to reliably tracking complication rates and identifying potential areas for improvement.

Functional Metrics: Integrating Objective Data (e.g., ROM, Validated Sensor Metrics)

Complementing subjective PROM data with objective functional measures can provide a more complete picture of recovery. Useful metrics collectable within a closed system include:

- **Clinician-Entered Range of Motion (ROM):** Standardized measurement of active or passive hip/knee flexion and extension recorded at baseline and specific post-operative follow-up points (e.g., 6 weeks, 3 months, 1 year).
- **Validated Wearable Sensor Metrics:** If specific, validated wearable technology is integrated into the system, objective data such as daily step counts, time spent walking or in moderate/vigorous activity, cadence, or potentially specific gait parameters (if validated algorithms are used) can be captured continuously or periodically during recovery.³⁰ This requires careful selection and validation of the technology as previously discussed.
- **Performance-Based Tests:** While less common as pure RWD due to the need for active administration, if standardized tests like the Timed Up and Go (TUG)²² or specific strength assessments are routinely performed as part of clinical care *within the system*, their results can be entered into structured fields.

Baseline Patient Factors: Demographics and Key Comorbidities Entered Directly

Understanding the baseline characteristics of the patient population is essential for risk adjustment and interpreting outcomes. The system should capture directly, rather than relying solely on potentially outdated external records:

- **Essential Demographics:** Age at surgery, sex, and Body Mass Index (BMI) are fundamental.¹³ Race and ethnicity should also be collected to assess potential disparities.⁶
- **Key Comorbidities and Risk Factors:** Clinically relevant conditions known to impact arthroplasty outcomes should be confirmed and recorded systematically. This includes diabetes, cardiovascular disease (history of MI, CHF), chronic pulmonary disease, chronic kidney disease, diagnosed depression or anxiety, smoking status, and potentially indicators of frailty or nutritional status.¹⁵ The ASA score provides a useful overall summary of physiological status.¹⁴



- **Mandated Risk Variables:** Variables required for external reporting programs, such as the CMS PRO-PM measure (which includes baseline general health via PROMIS-10/VR-12, back pain severity, health literacy proxy via SILS-2, and contralateral hip/knee pain ²⁸), serve as a minimum set of risk factors to capture.

Collecting these baseline factors directly within the system ensures consistency and relevance for risk-adjusted analyses performed on the internal RWE. While numerous data points could be collected, focusing effort on those demonstrably linked to TKA/THA outcomes, necessary for risk adjustment, critical for safety surveillance (like implant lot numbers), or essential for measuring patient-centered success (PROMs) is paramount. This strategic selection ensures the system generates high-value RWE without creating unsustainable data collection burdens. The CMS PRO-PM requirements ²⁴ provide a useful, externally validated starting point, which can be expanded based on the specific quality improvement priorities and research interests of the users within the closed system.

TABLE 2: PRIORITIZED CLINICALLY USEFUL DATA ELEMENTS FOR TKA/THA RWE IN A CLOSED SYSTEM

Data Element Category	Specific Data Type	Rationale for Clinical Utility	Collection Point
Demographics	Age at Surgery	Risk Adjustment, Subgroup Analysis	Pre-op
	Sex	Risk Adjustment, Subgroup Analysis	Pre-op
	BMI	Risk Adjustment, Outcome Prediction, Complication Risk	Pre-op
	Race / Ethnicity	Health Equity Assessment, Subgroup Analysis	Pre-op



TABLE 2: PRIORITIZED CLINICALLY USEFUL DATA ELEMENTS FOR TKA/THA RWE IN A CLOSED SYSTEM

Data Element Category	Specific Data Type	Rationale for Clinical Utility	Collection Point
Comorbidities	ASA Physical Status Classification	Overall Health Status, Risk Adjustment	Pre-op
	Diabetes Mellitus (Type 1/2, HbA1c if available)	Complication Risk (Infection), Outcome Prediction	Pre-op
	Smoking Status (Current, Former, Never)	Complication Risk (Wound, Infection), Outcome Prediction	Pre-op
	Diagnosed Depression/Anxiety	PROM Interpretation, Outcome Prediction	Pre-op
	Back Pain Severity	Risk Adjustment (CMS PRO-PM), Functional Outcomes	Pre-op
	Health Literacy Proxy (e.g., SILS-2)	Risk Adjustment (CMS PRO-PM), Patient Engagement	Pre-op
	Intra-op Details	Surgical Approach	Technique Comparison, Outcome Analysis
Fixation Method (Component Specific)		Technique Comparison, Implant Survival Analysis	Intra-op



TABLE 2: PRIORITIZED CLINICALLY USEFUL DATA ELEMENTS FOR TKA/THA RWE IN A CLOSED SYSTEM

Data Element Category	Specific Data Type	Rationale for Clinical Utility	Collection Point
	Use of Navigation/Robotics	Technology Assessment, Outcome Analysis	Intra-op
	Operative Duration	Efficiency Analysis, Potential Complication Correlation	Intra-op
	Anesthesia Type	Pathway Analysis, Outcome Correlation	Intra-op
	Intra-operative Complications (Standardized List)	Safety Monitoring, Quality Improvement	Intra-op
Implant Specifics	Component Manufacturer, Model, Size	Comparative Effectiveness, Performance Tracking	Intra-op
	Component Lot Number / Serial Number	Crucial for Safety Surveillance, Recall Management, Traceability	Intra-op
PROMs	KOOS JR / HOOS JR (or OKS/OHS)	Core Outcome Assessment (Pain, Function)	Pre-op, Post-op (e.g., 6wk, 3mo, 6mo, 1yr, 2yr+)
	PROMIS Global Health (or VR-12/EQ-5D)	Overall Health Status, Risk Adjustment (CMS PRO-PM)	Pre-op, Post-op (e.g., 6wk, 3mo, 6mo, 1yr, 2yr+)

TABLE 2: PRIORITIZED CLINICALLY USEFUL DATA ELEMENTS FOR TKA/THA RWE IN A CLOSED SYSTEM

Data Element Category	Specific Data Type	Rationale for Clinical Utility	Collection Point
	Patient Satisfaction	Patient-Centered Outcome Assessment	Post-op (e.g., 6mo, 1yr)
Functional Metrics	Clinician-Entered ROM (Flexion/Extension)	Objective Functional Assessment	Pre-op, Post-op (e.g., 6wk, 3mo, 1yr)
	Validated Sensor Data (e.g., Step Count, if implemented)	Objective Activity Level, Recovery Monitoring	Peri-operative (Continuous or Episodic)
Complications	Documented PJI (within system)	Safety Monitoring, Quality Improvement	Post-op (Ongoing)
	Documented VTE (within system)	Safety Monitoring, Prophylaxis Evaluation	Post-op (Typically within 90 days)
	Documented Dislocation (THA, within system)	Safety Monitoring, Technique/Implant Analysis	Post-op (Ongoing)
	Revision/Reoperation (within system, with reason)	Implant/Technique Survival, Quality Assessment	Post-op (Ongoing)



The true value of generating RWE within a proprietary closed system lies in its direct application to enhance clinical quality and patient outcomes within that specific ecosystem. Unlike RWE derived from broad, external sources, which often aims for generalizable conclusions or regulatory support, internally generated RWE provides highly relevant, actionable feedback for the participating clinicians and institutions. The high degree of data control, standardization, and validation inherent in a well-managed closed system fosters trust in the findings, making them more likely to be adopted for local practice changes.

Internal Performance Benchmarking: Surgeons, Techniques, and Implants

One of the most powerful applications is internal performance benchmarking.¹⁵ The standardized, validated data collected across all participating surgeons and sites within the system allows for meaningful comparisons of key outcomes. This can include:

- **Surgeon-Level Feedback:** Comparing risk-adjusted outcomes (e.g., PROM improvement scores, complication rates, revision rates for procedures performed within the system) among surgeons performing TKA/THA within the network. This requires careful risk adjustment using the detailed baseline patient factors collected. Identifying variations can highlight opportunities for shared learning and targeted support.
- **Technique Comparison:** Evaluating the outcomes associated with different surgical techniques employed *within the system*. For example, comparing patient-reported function or pain scores at one year for patients undergoing THA via an anterior versus a posterior approach, performed by the system's surgeons on the system's patient population.
- **Implant Performance Monitoring:** Tracking the performance of specific implant models or constructs used *within the participating sites*. This allows for internal comparative effectiveness analyses (e.g., does implant X lead to better OKS scores or lower revision rates than implant Y in our hands?) and rapid identification of any potential underperforming implants based on local data, complementing broader registry surveillance.¹⁴

This internal benchmarking moves beyond anecdotal experience, providing objective data reflecting actual practice and outcomes within the controlled environment of the closed system. Identifying both positive and negative outliers can drive targeted quality improvement efforts and foster a culture of continuous learning.



The true value of generating RWE within a proprietary closed system lies in its direct application to enhance clinical quality and patient outcomes within that specific ecosystem. Unlike RWE derived from broad, external sources, which often aims for generalizable conclusions or regulatory support, internally generated RWE provides highly relevant, actionable feedback for the participating clinicians and institutions. The high degree of data control, standardization, and validation inherent in a well-managed closed system fosters trust in the findings, making them more likely to be adopted for local practice changes.

Driving Comparative Effectiveness Insights Within the User Base

The granular data on patient characteristics, surgical techniques, and specific implants, linked directly to validated outcomes (PROMs, complications, function) within the same system, creates an ideal environment for internal comparative effectiveness research.⁷ This allows the users of the system to answer questions highly relevant to their own practice, such as:

Does using robotic assistance for TKA, compared to conventional instrumentation, result in better alignment (if measured and recorded), improved early functional recovery (PROMs, sensor data), or different complication profiles *among our surgeons and patients?*

For patients with specific characteristics (e.g., high BMI, significant pre-op deformity), does a particular implant design or fixation strategy yield superior long-term PROM scores or lower revision rates *within our cohort?*¹⁵

What is the impact of adopting a new perioperative pain management protocol or rehabilitation guideline *implemented across our system* on patient-reported pain scores, opioid consumption (if tracked), and functional milestones?¹⁸

These analyses provide evidence directly applicable to the decision-making of clinicians within the system, helping them choose the most effective approaches for their specific patient population based on local data, rather than relying solely on external studies conducted in potentially different settings with different patient groups.

Enhancing Longitudinal Patient Monitoring and Outcome Assessment

A closed system designed for long-term data capture enables comprehensive longitudinal monitoring of patient outcomes beyond the typical short-term follow-up.⁶ By systematically collecting PROMs and functional data at multiple time points (e.g., 1, 2, 5, even 10 years post-operatively, contingent on sustained patient engagement), the system can:

- Map Recovery Trajectories: Understand the typical course of improvement in pain, function, and activity levels following TKA and THA within the system's population, identifying when patients typically plateau.²⁷
- **Identify Long-Term Outcomes:** Assess the durability of implants and the persistence of functional gains over extended periods.
- **Subgroup Analysis:** Identify patient subgroups (based on baseline demographics, comorbidities, or surgical factors) who experience different recovery patterns or long-term outcomes, potentially highlighting needs for tailored interventions or expectations management.

This longitudinal perspective provides valuable insights into the long-term value and effectiveness of TKA/THA procedures as delivered within the system, going beyond simple implant survival metrics often found in registries.³⁶

Refining Localized Care Pathways and Protocols

The RWE generated internally serves as a powerful tool for evidence-based refinement of local clinical care pathways and protocols.¹⁸ By analyzing the relationship between specific process elements and observed outcomes within the system, administrators and clinical leaders can:

- **Evaluate Perioperative Protocols:** Assess the effectiveness of specific elements of the care pathway, such as pre-operative optimization strategies, anesthesia techniques¹⁷, pain management regimens¹⁸, DVT prophylaxis protocols¹⁴, and post-operative rehabilitation programs.³⁰ For instance, analyzing PROM data alongside pain protocol variations can inform optimization of pain management strategies used locally.
- **Inform Resource Allocation:** Identify areas where outcomes are suboptimal, potentially indicating a need for additional resources, staff training, or changes in clinical practice.
- **Standardize Best Practices:** Use the internal data to identify practices associated with the best outcomes *within the system* and promote their adoption across all participating providers and sites.

This application directly links data collection to tangible improvements in the efficiency and effectiveness of care delivery. Because the evidence is generated from the system's own patients and practices, it carries significant weight in driving local change. This contrasts with attempts to implement changes based solely on external guidelines or benchmarks, which may face resistance if perceived as irrelevant to the local context or based on data of questionable quality.¹¹



The internal RWE fosters a data-driven quality improvement cycle, creating a feedback loop where observed outcomes inform practice refinement, and the impact of those refinements is subsequently measured within the same system.

OPTIMIZING PATIENT-REPORTED OUTCOME MEASURE (PROM) COLLECTION VIA SYSTEM INTERFACES

Patient-Reported Outcome Measures (PROMs) are indispensable for capturing the patient's perspective, which is central to defining success in TKA and THA.¹⁴ These procedures aim not only to replace a joint but fundamentally to reduce pain, restore function, and improve overall quality of life – outcomes best assessed directly by the patient.²³ Furthermore, the collection of PROMs is increasingly mandated by payers and quality organizations, such as the Centers for Medicare & Medicaid Services (CMS) through its Inpatient Quality Reporting (IQR) and other programs for TKA/THA.²⁴ A proprietary closed system provides unique opportunities to streamline and optimize PROM collection directly through its integrated interfaces.

The Imperative of the Patient Voice: Why PROMs Matter

PROMs provide standardized, validated data on aspects of health that are inherently subjective and cannot be accurately captured through clinician observation or objective tests alone.²³ They allow quantification of symptoms like pain intensity and frequency, functional limitations in daily activities (e.g., walking, stair climbing, dressing)²⁴, joint stiffness, and overall physical and mental well-being.²² This patient-centered data is crucial for:

- **Evaluating Treatment Effectiveness:** Assessing whether the surgery achieved its primary goals from the patient's viewpoint.
- **Comparative Effectiveness Research:** Comparing how different implants, surgical techniques, or care pathways impact patient-perceived outcomes.¹⁰
- **Quality Improvement:** Identifying areas where patient outcomes may be lagging and informing efforts to improve care delivery.
- **Shared Decision-Making:** Helping set realistic expectations with future patients based on the outcomes experienced by similar patients within the system.



- **Meeting Reporting Requirements:** Fulfilling mandates from organizations like CMS that require PROM collection for public reporting and potentially value-based payment programs.²⁴

Effective Collection Modalities within the System (Portals, Tablets, Integrated Surveys)

A key advantage of a closed system is the ability to integrate PROM collection seamlessly into the patient's journey using various digital tools managed within the system. This avoids reliance on paper forms (prone to errors and delays) or disparate third-party survey platforms. Effective modalities include:

- **Secure Patient Portal:** Patients can log in from home or any internet-enabled device to complete PROM surveys at scheduled times (pre-operatively, various post-operative intervals). This offers convenience and flexibility for the patient. Success depends on patient access to technology and willingness to engage with the portal.
- **Clinic-Based Tablets:** Tablets deployed in waiting rooms or exam rooms allow for PROM completion during scheduled clinic visits. This ensures high capture rates for patients attending appointments and allows staff to provide assistance if needed. Potential drawbacks include patients feeling rushed or the possibility of the Hawthorne effect (altering responses due to being observed).
- **Integrated Mobile Application:** If the proprietary system includes a dedicated patient mobile app, PROM surveys can be delivered directly through the app, offering convenience and the potential for push notifications as reminders. This requires patients to own a compatible smartphone and actively use the app.³⁴
- **Automated Email/SMS with Secure Links:** The system can automatically send emails or text messages containing secure, unique links to PROM surveys at appropriate times. This pushes the task to the patient but relies on accurate contact information and patient responsiveness to the messages.²⁴

The optimal strategy often involves a combination of these modalities, tailored to the specific time point and patient population. For instance, a tablet might be ideal for capturing immediate pre-operative baseline data in the clinic, while the patient portal or email/SMS links might be more suitable for collecting 1-year or 2-year follow-up PROMs remotely.

Strategies to Maximize Patient Engagement and Data Completeness

Regardless of the modality chosen, maximizing patient engagement is critical for obtaining high completion rates, especially for longitudinal follow-up where attrition can be a significant issue.²⁷ Strategies facilitated by the closed system include:



- **Clear Communication:** Educating patients from the outset about why their input via PROMs is important for their own care and for improving care for future patients.
- **User-Friendly Interface:** Designing the PROM surveys within the portal, app, or tablet interface to be intuitive, easy to navigate, and visually appealing.
- **Automated Reminders:** Configuring the system to send automated reminders (via portal message, email, SMS, or app notification) to patients when PROM surveys are due.
- **Workflow Integration:** Embedding PROM collection into existing workflows, such as linking survey completion to appointment scheduling or telehealth visits conducted via the system.
- **Minimizing Burden:** Using the shortest validated versions of PROM instruments where appropriate (e.g., KOOS JR/HOOS JR, PROMIS Short Forms or CATs ²³) to reduce the time commitment required from patients.
- **Providing Feedback:** If feasible and appropriate, designing system features that allow patients to view their own PROM scores over time, potentially increasing motivation by showing progress.
- **Staff Support:** Training clinic staff to encourage PROM completion and assist patients who encounter difficulties with the technology.
- **Addressing Long-Term Attrition:** Developing specific protocols for persistent follow-up for longer-term PROMs, potentially involving phone calls (though this moves away from purely system-integrated collection) or targeted reminders. ³⁰

The integration capabilities of a closed system provide a distinct advantage here. By embedding PROM collection within the tools patients already use to interact with their healthcare providers (e.g., the patient portal for appointment scheduling or viewing results), the process can feel less like a separate research task and more like a natural part of their ongoing care. ³⁴ This contextual integration has the potential to significantly improve compliance and the quality of patient-reported data compared to standalone PROM initiatives.

Furthermore, while external mandates like those from CMS prescribe specific PROM instruments and collection windows ²⁶, a proprietary system offers the flexibility to go beyond these minimums. The system's users can choose to incorporate additional validated PROMs (e.g., the Forgotten Joint Score ²², specific activity level scales ²⁷, or more detailed quality of life measures) that align with their specific internal research questions or quality improvement goals. This allows for a richer, more nuanced understanding of patient outcomes tailored to the interests of the clinicians and researchers within the closed ecosystem, balancing the need for standardized data with the desire for deeper clinical insights.



TABLE 3: COMPARISON OF PROM COLLECTION MODALITIES WITHIN THE CLOSED SYSTEM

Modality	Pros	Cons	Best Use Case within System	Key System Requirements
Integrated Web Portal Survey	Patient convenience (anytime, anywhere access), Reduced staff burden, Secure environment	Requires patient internet access & portal registration/engagement, Potential for lower response rates without reminders	Pre-op baseline, Longitudinal follow-up (e.g., 1yr, 2yr+)	Secure patient portal infrastructure, User authentication, Automated survey deployment/reminders
Tablet-based in Clinic	High initial compliance during visits, Staff assistance available, Immediate data entry	Potential for patients feeling rushed, Possible Hawthorne effect, Requires hardware & clinic workflow integration	Pre-op baseline, Immediate post-op @ discharge, Early follow-up visits (e.g., 6wk)	Tablet hardware, Secure Wi-Fi, Kiosk mode software, Staff training, Workflow integration
Automated Email/SMS Secure Link	Pushes survey directly to patient, Can reach patients not actively using portal, Relatively low cost	Relies on accurate/updated contact info, Patient action required, Potential security/phishing concerns	Longitudinal follow-up, Reaching less tech-savvy patients (if SMS preferred)	Validated email/phone capture, Secure link generation, SMS gateway (for texts), Reminder system
Integrated Mobile App Survey	High convenience for app users, Potential for push notifications/reminders, Can integrate with other app features	Requires smartphone ownership & app download/usage, Potential app fatigue/adoption barriers	Pre-op, Post-op intervals for engaged app users	Proprietary mobile app development/integration, Secure authentication, Push notification capability



The credibility and utility of RWE generated from any source depend fundamentally on the quality of the underlying RWD.¹ A proprietary closed system presents a unique opportunity to build data quality assurance mechanisms directly into the data collection and management processes, moving beyond the reactive data cleaning often required for external RWD sources.⁵ Establishing and maintaining high data integrity is paramount for generating trustworthy RWE that can confidently inform clinical practice and quality improvement initiatives within the system.

Establishing Robust Data Dictionaries and Standardization Protocols

Consistency in data definition and collection is foundational to data quality. A closed system must implement:

- **Comprehensive Data Dictionary:** A central document or repository that meticulously defines every single data element collected within the system. This includes a clear variable name, an unambiguous definition, the data type (e.g., date, integer, text, categorical), allowed values or formats (e.g., specific date format, range of permissible numeric values), units of measure (e.g., degrees for ROM, kg/m² for BMI), and the source/method of collection.¹⁴ This dictionary serves as the blueprint for data collection and ensures everyone using the system understands precisely what each field represents.
- **Standardized Terminologies:** Wherever feasible, the system should enforce the use of standardized clinical terminologies and coding systems. This might include using ICD codes for diagnoses, CPT codes for procedures (though the system will capture more granular detail), standardized naming conventions for surgical approaches or implant types, and potentially SNOMED CT for specific clinical findings. This facilitates internal consistency and improves the potential for future interoperability or comparison with external datasets, if ever needed.
- **Uniform Collection Protocols:** Clearly defined procedures for how and when data should be collected and entered into the system across all participating users and sites. This ensures that data elements are captured consistently, regardless of who is entering the information.

Implementing Automated Validation Rules and Data Quality Checks

Leveraging the system's software capabilities to perform automated checks at the point of data entry is a highly effective way to prevent errors and ensure data integrity:

- **Format and Range Checks:** Rules that ensure data is entered in the correct format (e.g., YYYY-MM-DD for dates) and falls within plausible ranges (e.g., preventing entry of an age of 200 or a negative BMI).¹

- **Logic Checks:** Rules that verify the logical consistency between different data fields. For example, a rule might prevent recording a revision TKA procedure if no prior primary TKA is documented for that patient within the system, or flag inconsistencies between laterality recorded and the specific joint indicated in the procedure description.
- **Completeness Checks:** Identifying mandatory fields that must be filled before a record can be saved or finalized. This ensures that critical data points (e.g., implant lot numbers, baseline PROMs) are not inadvertently omitted.
- **Cross-Field Validation:** More complex rules that check consistency across multiple related fields. For instance, ensuring that the selected implant components are compatible with each other based on manufacturer specifications embedded in the system's logic.

These automated checks provide real-time feedback to users, catching potential errors immediately and significantly improving the quality of the raw data captured.

Internal Auditing, Monitoring, and Feedback Loops

Data quality assurance is not a one-time setup; it requires ongoing monitoring and refinement:

- **Regular Data Audits:** Periodically conduct internal audits to assess data accuracy and completeness. This might involve comparing a sample of system entries against primary source documents *that are accessible within the system's environment* (e.g., scanned operative notes, integrated pathology reports, clinician notes entered directly into the system). This internal source data verification (SDV) differs fundamentally from the challenge of validating against external, inaccessible EHRs.
- **Data Quality Monitoring and Reporting:** Generate regular reports that summarize key data quality metrics, such as field completion rates, frequency of data entry errors flagged by validation rules, and data consistency across sites or users. These reports should be shared with relevant stakeholders (clinicians, administrators, data managers).
- **Feedback and Correction Mechanisms:** Establish clear processes for identifying, reporting, and correcting data errors or omissions discovered through audits or monitoring. This feedback loop helps improve both the data itself and the data entry practices of users.
- **Ongoing Training and Support:** Provide regular training refreshers and readily available support for staff on data entry protocols, the importance of data quality, and how to use the system's features correctly.

This continuous cycle of monitoring, auditing, feedback, and training is essential for maintaining high data quality over the long term. The ability to proactively design, implement, and enforce these quality measures from the ground up represents perhaps the most significant advantage of a closed system for RWE generation. External RWD sources, often collected for purposes other than research (like billing or routine clinical documentation), inherently contain biases, errors, and inconsistencies that require extensive, often imperfect, post-hoc cleaning.¹

A proprietary closed system, if designed and managed appropriately, can embed quality controls directly into the data capture workflow, shifting the focus from reactive data cleaning to proactive data quality assurance by design. This results in a more trustworthy foundation for generating reliable RWE. However, this requires sustained organizational commitment, dedicated resources for data management and governance, and continuous vigilance to prevent data quality degradation over time as systems evolve and user practices change.

TABLE 4: DATA QUALITY ASSURANCE STRATEGIES FOR A CLOSED SYSTEM

Strategy	Description	Implementation within Closed System	Impact on RWE Reliability
Standardized Data Dictionary	Central, comprehensive definition for every data element (name, definition, type, format, allowed values, units).	Maintained within system documentation; enforced through interface design (picklists, structured fields based on dictionary).	Ensures consistent interpretation and recording of data across users/sites; reduces ambiguity.
Automated Validation Rules	System-enforced checks at data entry (range, logic, format, completeness, cross-field consistency).	Built into the software application's data entry forms and database constraints.	Prevents common errors in real-time; improves accuracy and completeness of raw data.



TABLE 4: DATA QUALITY ASSURANCE STRATEGIES FOR A CLOSED SYSTEM

Strategy	Description	Implementation within Closed System	Impact on RWE Reliability
Internal Source Data Verification (SDV) Sampling	Periodic comparison of a sample of system data entries against accessible primary source documents within the system's environment.	Manual or semi-automated process performed by data quality team, comparing system fields to scanned notes, integrated reports etc.	Verifies accuracy of data entry beyond automated checks; identifies systematic errors or areas needing improved training.
User Training & Support Protocols	Initial and ongoing training on data definitions, collection protocols, system usage, and the importance of data quality.	Formal training sessions, online modules, readily available documentation, helpdesk support.	Improves user understanding and adherence to protocols; reduces inadvertent errors.
Regular Data Quality Audits & Reporting	Systematic reviews of data quality metrics (completeness, consistency, error rates) with reports generated for stakeholders.	Automated scripts generating quality dashboards/reports; manual review processes focusing on key data elements.	Identifies trends in data quality issues; provides basis for targeted interventions and tracks improvement over time.
Data Governance Framework	Established policies, procedures, and responsibilities for data quality management, data access, and system changes.	Formal governance committee or designated roles; documented policies accessible to users.	Ensures accountability and systematic approach to maintaining data integrity throughout the system's lifecycle.



While offering distinct advantages in data control and quality, generating RWE exclusively within a proprietary closed system also presents unique challenges and inherent limitations that must be acknowledged and managed. Understanding these constraints is crucial for interpreting the evidence generated and setting realistic expectations about its applicability.

Addressing Potential Selection Bias and Limited Generalizability

Perhaps the most significant limitation is the potential for selection bias and the resulting constraint on the external generalizability of findings.¹ The population of patients, surgeons, and institutions participating in or captured by the proprietary system may not be representative of the broader TKA/THA population encountered in diverse healthcare settings. Factors influencing participation might include:

- **Patient Characteristics:** The system might predominantly capture patients from specific geographic areas, socioeconomic strata, or insurance plans served by the participating network. Patients lacking access to these providers are excluded.
- **Provider Characteristics:** Surgeons or hospitals choosing to use the proprietary system may differ systematically from those who do not (e.g., academic vs. community practice, early adopters of technology vs. late adopters, specific subspecialty interests).
- **System Design:** The very features or focus of the system might attract certain types of users or be implemented in specific types of clinical environments.

Consequently, findings derived from this RWE – such as the observed performance of a particular implant, the effectiveness of a specific surgical technique, or the typical patient recovery trajectory – may be highly valid *within the context of the closed system* but cannot automatically be assumed to apply universally.⁶ The unique mix of patients, provider expertise, and specific clinical practices within the system influences the outcomes observed. Mitigation strategies involve:

- **Transparency:** Clearly and comprehensively reporting the demographic and clinical characteristics of the patient cohort included in any analysis generated from the system.
- **Acknowledging Limitations:** Explicitly stating the potential for selection bias and the limitations regarding the generalizability of findings to populations or settings outside the closed system in all reports and publications. The strength lies in understanding *what works best within this specific context*, not necessarily in making universal claims.

Strategies for Sustaining Long-Term Patient Engagement and Data Collection

Collecting longitudinal data, particularly PROMs, over multiple years post-surgery is vital for understanding long-term outcomes but poses significant challenges.²⁷ Patient attrition is common; individuals may move, lose interest, experience survey fatigue, or simply be difficult to contact years after their procedure. This attrition is rarely random and can introduce bias into long-term analyses, as patients with poorer outcomes may be less likely to respond. Sustaining engagement requires proactive and persistent effort:

- **Streamlined Processes:** Making PROM completion as easy and minimally burdensome as possible using user-friendly interfaces and optimized survey lengths.²⁵
- **Multi-modal Reminders:** Utilizing the system's capabilities for automated reminders via multiple channels (portal, email, SMS, app notifications).²⁴
- **Demonstrating Value:** Communicating to patients how their continued participation contributes to improving care for others and potentially provides insights into their own long-term joint health.
- **Dedicated Resources:** Allocating staff time or resources specifically for managing long-term follow-up efforts, potentially including personalized outreach for non-responders.
- **Ethical Incentives:** Considering small, ethically approved incentives for completing long-term follow-up surveys, if deemed appropriate and feasible within the system's operational context.

Despite best efforts, some level of attrition is inevitable, and its potential impact on long-term findings must be considered during analysis and interpretation.

Data Curation, Maintenance, and Scalability Considerations

A closed data system is not a static entity; it requires ongoing technical and operational support:

- **Data Curation and Storage:** Managing the secure storage, backup, and archiving of large and growing datasets over many years requires robust IT infrastructure and adherence to data privacy regulations (e.g., HIPAA in the US).
- **System Maintenance and Updates:** Ensuring the software remains functional, secure, and up-to-date requires regular maintenance, patching, and potentially significant upgrades over time. Data migration strategies may be needed to ensure continued usability as technology evolves.
- **Scalability:** The system's architecture must be able to handle growth if the number of users, participating sites, or data volume increases significantly. Planning for scalability from the outset is important.

These operational aspects require sustained financial and personnel investment from the organization hosting the closed system.

While the primary focus of a closed system is internal data generation and use, it is prudent to consider potential future needs for interoperability, even if not an immediate goal. Situations might arise where comparing internal findings to external benchmarks, participating in multi-center research collaborations, or linking internal data to external sources (e.g., national mortality databases, though this breaches the strict "closed" definition) becomes desirable.

Designing the system with adherence to common data standards (e.g., using standardized terminologies like ICD or SNOMED CT where possible, structuring data in recognized formats) can facilitate such future integration if required.⁶ While maintaining the integrity of the closed system is paramount, building in flexibility through standardization can prevent future roadblocks if external connections or comparisons become necessary.

In essence, the trade-off for the high internal validity and data control offered by a closed system is a reduction in external generalizability and the assumption of a significant, ongoing operational burden. Recognizing these limitations and proactively managing the associated challenges are key to maximizing the system's value and ensuring its long-term sustainability and success. Failure to invest in patient engagement, data curation, system maintenance, and robust governance will inevitably lead to degradation of the data quality and trustworthiness that form the system's core advantage.

Advanced Analytics (AI/ML) on Validated Internal Data: Unlocking Deeper Insights

The high-quality, granular, and relatively complete datasets generated within a well-managed proprietary closed system provide an exceptional foundation for applying advanced analytical techniques, including Artificial Intelligence (AI) and Machine Learning (ML).⁶ While traditional statistical methods remain valuable, AI/ML can potentially uncover more complex patterns, generate predictive models, and ultimately help personalize care for the specific patient population served by the system.

The principle of "garbage in, garbage out"¹ strongly applies to AI/ML; therefore, using the validated, high-integrity data from a closed system can yield more reliable and clinically relevant insights compared to models trained on larger but often "dirtier" external datasets.

Predictive Analytics for Patient Outcomes and Risk Stratification

One promising application is the development of predictive models tailored to the system's population:

- **Outcome Prediction:** Using the rich baseline data (demographics, detailed comorbidities, pre-op PROMs, potentially functional metrics) and surgical data (technique specifics, implant choice) collected within the system, ML algorithms can be trained to predict key patient outcomes at specific time points. Examples include predicting a patient's likely 1-year KOOS JR or HOOS JR score, the probability of achieving a Minimal Clinically Important Difference (MCID) or Substantial Clinical Benefit (SCB)²⁴, or the likelihood of experiencing prolonged recovery.
- **Risk Stratification:** Models can be developed to predict the risk of specific adverse events, such as PJI, VTE, revision surgery within a certain timeframe, or hospital readmission, based on patient and procedural factors documented in the system.⁶ This allows for the identification of high-risk patients *within the system's cohort* who might benefit from targeted preventive measures, intensified monitoring, or modified care pathways.

These predictive tools, developed and validated on the system's own data, can support pre-operative patient counseling by setting more realistic, data-driven expectations and aid clinicians in tailoring perioperative management strategies.

Identifying Subtle Patterns for Technique and Implant Optimization

AI/ML techniques, particularly unsupervised learning (e.g., clustering) or advanced supervised learning algorithms, can identify complex, non-linear relationships and interactions within the data that might be missed by conventional analyses¹⁰:

- **Uncovering Complex Interactions:** ML models might reveal that a specific combination of patient factors (e.g., age > 75, BMI > 35, pre-op flexion contracture > 10 degrees) combined with a particular surgical technique (e.g., specific ligament balancing sequence) and implant type leads to significantly different outcomes compared to other combinations – patterns that simple bivariate or linear regression analyses might not detect.
- **Optimizing Choices for Subgroups:** Identifying which specific surgical approaches, implant designs, or fixation methods yield the best results for distinct patient subgroups defined by multiple characteristics captured within the system's detailed dataset.
- **Analyzing Sensor Data Patterns:** If validated wearable sensor data is integrated, ML could analyze patterns in activity recovery (e.g., rate of increase in step count, changes in gait metrics over time) to identify signatures associated with optimal outcomes or early signs of complications.³¹

These insights can guide surgeons in refining their techniques or making more nuanced implant choices for specific patient profiles encountered *within their practice*.



Personalizing Care within the System's Patient Population

The ultimate goal of applying AI/ML in this context is often personalization of care:

- **Tailored Expectations:** Using predictive models to provide patients with individualized projections of their likely recovery trajectory and final outcome based on data from highly similar patients within the system's database.
- **Personalized Rehabilitation:** Potentially using predicted recovery patterns or real-time sensor data feedback loops (if implemented) to guide adjustments to post-operative rehabilitation protocols, tailoring intensity or focus based on individual progress.³¹
- **Decision Support:** Developing clinical decision support tools integrated into the system's workflow that leverage AI/ML models to provide clinicians with risk assessments or outcome predictions at the point of care, aiding in treatment planning.

Leveraging NLP for Unstructured Data (If Applicable)

While the emphasis in a closed system is often on structured, validated data, some systems may incorporate structured templates that allow for limited free-text entry within specific fields (e.g., descriptions in operative notes, reasons for revision). If such text data is captured consistently and can be reliably linked to outcomes, Natural Language Processing (NLP) techniques could potentially be applied *within the system* to extract additional nuanced information.¹⁰

For example, NLP might identify specific surgical findings, reasons for deviation from standard protocol, or patient-reported symptoms described in narrative form. However, implementing NLP requires significant expertise and careful validation to ensure the extracted information is accurate and reliable, potentially pushing the boundaries of a strictly validated, structured data environment. Its application should be approached cautiously and rigorously validated within the system's context.

It is crucial to reiterate that AI/ML models and the insights derived from them using closed-system data are primarily applicable *within that system*. The models are trained on the specific characteristics, practice patterns, and potential biases inherent in that unique data ecosystem.

While they can be powerful tools for internal optimization, personalization, and discovery relevant to the system's users and patients, their predictive accuracy and the relevance of identified patterns may diminish significantly if applied externally to different populations or clinical settings due to the inherent limitations in generalizability.¹¹ The focus should remain on leveraging these advanced analytics to generate actionable insights that drive improvements locally.



The generation of Real-World Evidence (RWE) exclusively within the confines of a proprietary closed data system offers a distinct and valuable approach for advancing the quality of care in Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA). By prioritizing internal data generation, rigorous validation, and standardized collection protocols, such systems can produce highly reliable and clinically relevant evidence, albeit with inherent limitations regarding external generalizability.

The shift in focus from broad applicability to high internal validity allows for the creation of a powerful feedback loop, enabling participating clinicians and institutions to objectively assess their own practices, compare the effectiveness of different techniques and implants used locally, monitor patient outcomes longitudinally with high fidelity, and drive targeted quality improvement initiatives based on trustworthy local data.

The success of leveraging a closed system for RWE generation hinges on several critical factors. Paramount among these are strong data governance structures, an unwavering organizational commitment to maintaining data quality through robust validation and auditing processes, and the implementation of effective, user-friendly strategies for collecting patient-reported data, particularly PROMs, over the long term. Engaging clinicians and patients, ensuring the system's technical robustness and scalability, and transparently acknowledging the system's limitations, especially concerning selection bias, are also essential components for success.

Based on the analysis presented, the following strategic recommendations are provided for organizations implementing or utilizing proprietary closed data systems for TKA/THA RWE:

- **Prioritize Granular, Validated Data Collection:** Focus system design and data entry protocols on capturing detailed, accurate information on patient baseline characteristics (including mandated risk variables), specific implant identifiers (including lot/serial numbers), key surgical technique variables, clinician-entered functional metrics (like ROM), and systematically collected PROMs using validated instruments at standardized intervals.
- **Embed Rigorous Data Quality Assurance:** Implement comprehensive data dictionaries, automated validation rules at the point of entry, regular internal data audits (including sampling for source data verification within the system), and continuous user training to ensure the highest possible data integrity from the outset. Data quality should be a core design principle, not an afterthought.
- **Optimize PROM Collection and Engagement:** Invest in user-friendly, integrated system interfaces (portals, tablets, apps) for direct PROM capture. Employ multi-modal strategies and automated reminders to maximize patient engagement and minimize attrition, particularly for crucial long-term follow-up. Clearly communicate the value of PROM participation to patients.



- **Leverage RWE for Internal Improvement Cycles:** Actively utilize the generated RWE for internal benchmarking of surgeons, techniques, and implants. Conduct internal comparative effectiveness analyses relevant to local practice patterns. Use the findings to systematically evaluate and refine perioperative care pathways and protocols. Foster a data-driven culture of continuous learning and improvement.
- **Explore Advanced Analytics Cautiously:** Consider the application of AI/ML techniques on the high-quality internal data to develop predictive models for risk stratification and outcome prediction, identify subtle patterns for optimizing care, and personalize treatment approaches for the system's specific patient population. Ensure rigorous validation of any models developed.
- **Maintain Transparency Regarding Limitations:** Always report findings generated from the closed system with clear descriptions of the patient cohort and explicit acknowledgment of potential selection biases and limitations in external generalizability.
- **Ensure Sustained Organizational Commitment:** Recognize that maintaining a high-quality closed data system requires ongoing investment in technology, data management resources, governance structures, and strategies for long-term patient engagement. Secure sustained organizational support to ensure the system's long-term viability and value.

By adhering to these principles, organizations can harness the unique potential of proprietary closed data systems to generate trustworthy RWE that directly informs and improves the quality, safety, and patient-centeredness of TKA and THA care within their specific clinical environment.



1. Real world evidence - Wikipedia, accessed April 23, 2025, https://en.wikipedia.org/wiki/Real_world_evidence
2. Real-World Evidence - FDA, accessed April 23, 2025, <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>
3. www.fda.gov, accessed April 23, 2025, <https://www.fda.gov/science-research/real-world-evidence/center-biologics-evaluation-and-research-center-drug-evaluation-and-research-real-world-evidence#:~:text=As%20defined%20by%20FDA%2C%20real,derived%20from%20analysis%20of%20RWD>
4. Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products - FDA, accessed April 23, 2025, <https://www.fda.gov/media/171667/download>
5. FDA Real-World Evidence: What Does It Really Mean and How Does It Work? - NAMSA, accessed April 23, 2025, <https://namsa.com/resources/blog/fda-real-world-evidence/>
6. Real-World Data: What Is It and Why Does It Matter? - Datavant, accessed April 23, 2025, <https://www.datavant.com/real-world-data>
7. Real-World Evidence: A Primer - PMC - PubMed Central, accessed April 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC9815890/>
8. Center for Biologics Evaluation and Research & Center for Drug Evaluation and Research Real-World Evidence | FDA, accessed April 23, 2025, <https://www.fda.gov/science-research/real-world-evidence/center-biologics-evaluation-and-research-center-drug-evaluation-and-research-real-world-evidence>
9. Framework for FDA's Real-World Evidence Program, accessed April 23, 2025, <https://www.fda.gov/media/120060/download>
10. EHR Data and Real-World Examples | Datavant, accessed April 23, 2025, <https://www.datavant.com/real-world-data-rwd/ehr-data-real-world-examples>
11. Building the Pathway to Successful Use of RWE - BONEZONE, accessed April 23, 2025, <https://bonezonepub.com/2024/01/15/building-the-pathway-to-successful-use-of-rwe/>
12. A Review of Real-World Data Sources Used in Orthopaedic Research - PubMed, accessed April 23, 2025, <https://pubmed.ncbi.nlm.nih.gov/33587540/>
13. A Systematic Review of Data Collection by National Joint Replacement Registries: What Opportunities Exist for Enhanced Data Collection and Analysis? - PubMed, accessed April 23, 2025, <https://pubmed.ncbi.nlm.nih.gov/37956205/>
14. International Registries - JBJS, accessed April 23, 2025, https://www.jbjs.org/reader.php?rsuite_id=3471485
15. Electronic Data Capture through Total Joint Replacement Registries - PMC, accessed April 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC4371429/>
16. Computer-Assisted Surgical Navigation for Musculoskeletal Procedures – Commercial and Individual Exchange Medical Policy - UHCprovider.com, accessed April 23, 2025, <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/computer-assisted-surg-nav-musculoskeletal-procs.pdf>

17. Comparing Anesthesia and Surgery Controlled Time for Primary Total Knee and Hip Arthroplasty Between an Academic Medical Center and a Community Hospital: Retrospective Cohort Study - JMIR Perioperative Medicine, accessed April 23, 2025, <https://periop.jmir.org/2024/1/e45126/>
18. Implementation of a Total Joint Replacement-Focused Perioperative Surgical Home: A Management Case Report, accessed April 23, 2025, <https://www.asahq.org/psh/~media/sites/psh/files/psh-total-joint-replacement-year1.pdf>
19. Total Joint Arthroplasty Time-of-Day Start Time Has Minimal Effect on Intraoperative Efficiency, accessed April 23, 2025, <https://journaloei.scholasticahq.com/article/72786-total-joint-arthroplasty-time-of-day-start-time-has-minimal-effect-on-intraoperative-efficiency>
20. INTRAOPERATIVE EVALUATION AND LEVEL OF CONTAMINATION DURING TOTAL KNEE ARTHROPLASTY - PMC, accessed April 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC9270042/>
21. Total Joint Replacement Perioperative Surgical Home Program: 2-Year Follow-Up | Request PDF - ResearchGate, accessed April 23, 2025, https://www.researchgate.net/publication/304072314_Total_Joint_Replacement_Periooperative_Surgical_Home_Program_2-Year_Follow-Up
22. The current utilization of the patient-reported outcome measurement information system (PROMIS) in isolated or combined total knee arthroplasty populations, accessed April 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC9850535/>
23. Patient-reported outcomes after hip and knee arthroplasty: results from a large national registry, accessed April 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC8244799/>
24. What Healthcare Orgs Must Know: CMS's Recent Patient Reported Outcomes Mandates, accessed April 23, 2025, <https://www.memorahealth.com/news/what-healthcare-orgs-must-know-cmss-recent-patient-reported-outcomes-mandates>
25. Common Patient-Reported Outcome Measures for Knee Arthroplasty Patients | Request PDF - ResearchGate, accessed April 23, 2025, https://www.researchgate.net/publication/356413454_Common_Patient-Reported_Outcome_Measures_for_Knee_Arthroplasty_Patients
26. Clinician-Level and Clinician Group-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA and TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) | Partnership for Quality Measurement, accessed April 23, 2025, <https://p4qm.org/measures/3639>
27. Patient-reported outcome scores over time for total knee arthroplasty. - ResearchGate, accessed April 23, 2025, https://www.researchgate.net/figure/Patient-reported-outcome-scores-over-time-for-total-knee-arthroplasty_tbl2_337511406
28. The Mandatory Centers for Medicare & Medicaid Services Inpatient Quality Reporting Total Hip Arthroplasty/Total Knee Arthroplasty Patient-reported Outcomes Performance Measure | American Academy of Orthopaedic Surgeons, accessed April 23, 2025, <https://www.aaos.org/registries/quality-collaborations/iqr-resources/>
29. Mandatory CMS Inpatient THA/TKA PRO-PM Frequently Asked Questions, accessed April 23, 2025, <https://www.aaos.org/globalassets/quality-and-practice-resources/patient-reported-outcome-measures/pro-pm-frequently-asked-questions-fact-sheet.pdf>

30. Wearable Sensors to Aid Rehabilitation Following Total Knee Arthroplasty: Experiences of Trial Participants - PMC, accessed April 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC12004422/>
31. The potential of wearable technology in knee arthroplasty | Request PDF - ResearchGate, accessed April 23, 2025, https://www.researchgate.net/publication/384437921_The_potential_of_wearable_technology_in_knee_arthroplasty.
32. Feasibility of continuous physical activity monitoring: first-month recovery markers following joint replacement surgery - PeerJ, accessed April 23, 2025, <https://peerj.com/articles/18285.pdf>
33. Wearable Sensors to Guide Remote Rehabilitation Following Knee Arthroplasty Surgery, accessed April 23, 2025, <https://pmc.ncbi.nlm.nih.gov/articles/PMC10147850/>
34. The role of commercially available smartphone apps and wearable devices in monitoring patients after total knee arthroplasty: a systematic review in, accessed April 23, 2025, <https://eor.bioscientifica.com/view/journals/eor/7/7/EOR-21-0115.xml>
35. Safety notices and registry outlier data measure different aspects of safety and performance of total knee implants: a comparative study of safety notices and register outliers | Acta Orthopaedica, accessed April 23, 2025, <https://actaorthop.org/actao/article/view/42361>
36. Overview of the Global Orthopaedic Registry (GLORY), accessed April 23, 2025, <https://cdn.mdedge.com/files/s3fs-public/Document/September-2017/039090002s.pdf>
37. American Joint Replacement Registry - AAOS, accessed April 23, 2025, <https://www.aaos.org/registries/american-joint-replacement-registry/>

