Project Protocol

Improvement of Patient Satisfaction and Clinical Outcomes Using JointCOACH to Manage the Episode of Care for THA and TKA Bundles

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1. Project Summary

JointCOACH is a web-based communication platform that enables joint replacement patients to communicate with their care team via computer or smartphone throughout their episode of care, from the time that surgery is scheduled until at least 90 days postoperatively. Patients will receive the following information at key intervals: 1) instructions about how to prepare for surgery, 2) information about the procedure, 3) information about medications and pain control, 4) information about postoperative recovery and rehabilitation. In addition, several surveys will be distributed using JointCOACH to keep patients involved in their own recovery and to keep the surgical team informed of their progress. The proposed research will help determine if JointCOACH can improve patient satisfaction and clinical outcomes.

2. Introduction and Background

Health systems invest significant resources to improve quality and reduce costs. However, this process is typically driven by hospital administration and staff. Recently, studies have shown that when patients are engaged, they take more responsibility for their own health and preventative care. Additionally, these patients are more satisfied with their healthcare experiences and have lower rates of healthcare utilization [1,2]. Physicians are in the best position to promote patient engagement since they have direct relationships with their own patients. However, physicians need frictionless tools with minimal implementation barriers in order to create and maintain this relationship in the follow up period.

Patient engagement has been referred to as the next blockbuster "drug", and increasing evidence demonstrates that highly engaged patients not only enjoy improved outcomes, but have fewer complications, undergo fewer readmissions, and have lower total costs of care [3–5]. While these engagement-related outcomes have been shown in several other specialties, relatively little has been done to explore this relationship in orthopedics. The opportunity to demonstrate the

impact of engagement on outcomes in the orthopedic space is highlighted by the estimated $1.5B of medical expenses occurring nationally due to potentially preventable readmissions following orthopedic surgeries alone.

Stryker Performance Solutions JointCOACH™ and the Cleveland Clinic are interested in collaborating on a clinical pilot study to demonstrate that high patient engagement leads to enhanced preoperative preparation potentially reducing length of stay (LOS), readmissions and reoperations, increasing discharge disposition to home rather than another facility, reducing the need for in-person follow up, and increasing patient (and provider) satisfaction after elective primary hip and knee arthroplasty (THA and TKA). These improvements can translate to higher financial savings through the episode of care especially in light of the alternative payment models.

3. Specific Aims

Currently in use by orthopedic groups around the country, JointCOACH improves perioperative outcomes after THA and TKA and mitigates risk by: 1) enhancing patient engagement with providers, 2) allowing patients to play an integral role in patient-reported outcomes, 3) generating and relaying actionable pre- and postoperative reporting directly to the clinical team, and 4) detecting impending postoperative complications early, enabling timely intervention and preventing avoidable complications and readmissions. The specific aims of this proposal are to:

1. Measure patient satisfaction with and without use of JointCOACH as a tool for patient engagement

2. Understand the degree to which high postoperative engagement can reduce the amount of healthcare resource utilization by answering the following questions:

a. Will the use of JointCOACH decrease the number of potentially avoidable healthcare utilization encounters such as Emergency Department (ED) and hospital visits (i.e. readmissions and reoperations)?

b. Does utilizing JointCOACH improve clinical workflow by minimizing telephone calls and thereby offloading support staff, allowing them to be more efficient?

c. Does utilizing JointCOACH reduce the volume of on-call pages by addressing patient questions up front, alleviating concerns, and providing them with the information they need when they need it?

d. Does utilizing JointCOACH allow the practice to identify patients whose in-person follow-up needs are minimal?

3. Measure additional potential benefits including shorter length of hospital stay, discharge disposition to home rather than a facility and decreased 90 day readmissions and reoperations by answering the following:

a. Does utilizing JointCOACH lead to early detection of adverse signs/symptoms that develop between clinical encounters and result in reduced readmissions and reoperations?

4. Evaluate the financial impact of JointCOACH in the episode of care (% difference in Charges between JointCOACH and standard of care groups)

4. Methods

4.1 Study Design

The study design is a prospective, randomized trial in which patients undergoing elective primary hip or knee arthroplasty will be offered perioperative use of JointCOACH vs standard of care. A total of 400 patients will be enrolled (200 in each group). The following outcome measures will be collected at the intervals specified in the Schedule of Events:

- Demographics (Age, gender, BMI)

- Comorbidities (Age-Adjusted Charlson Comorbidity Index)

- Surgical details (ASA (or other comorbidity index), Length of surgery (incision to closure), procedure type, operative limb, surgeon)

- Length of hospital stay and discharge disposition

- Number of ED visits and follow-up visits within 90 days

- Number of phone calls and on-call pages within 90 days

- Readmissions and reoperations within 90 days

- Patient satisfaction (VAS satisfaction and PPE-15)

- Provider satisfaction (5-point Likert scale)

4.2 Patient Population

The Cleveland Clinic Orthopedic Institute practice patients from Main Campus surgeons (Mesko, Krebs, Greene, Kamath, Piuzzi), Lutheran Hospital surgeons (Mesko, Krebs), Marymount surgeons (Kamath, Piuzzi), and Medina Hospital surgeons (Greene) will be assessed for eligibility.

Inclusion criteria

1. Undergoing primary total hip or primary total knee arthroplasty

2. Willing to sign an IRB approved informed consent form

3. Have internet access or mobile access with a valid email address at the time of enrollment

4. Above the age of 18 years

Exclusion criteria

1. Staged arthroplasty procedure within 6 months of the index procedure

2. Abandoned email address of record (e.g. bounce of email from clinic)

3. Planned discharge to a Skilled Nursing Facility

4.3 Sample Size Calculation

We will enroll 400 patients (200 in each group). This sample size was estimated using patient reported satisfaction based on the PPE-15 questionnaire as the primary endpoint. Currently, it is not known what will be a clinically relevant difference so we conservatively estimated that a 10% difference in patient satisfaction (difference in % of respondents indicating a problem on the PPE-15 between treatment and control groups) would be relevant. Based on data published in a study by Jenkinson et al, we used a mean of 24.7% (± 7.7) for the percent of respondents across all PPE-15 domains that identified a problem with their experience[6]. Setting alpha equal to 0.05 and power equal to 80%, we determined that we will need 153 patients in each group. However, we will enroll 200 patients in each group to account for withdrawals and non-responders.

4.4 Schedule of Events

Evaluation	Preop	Intraop	Inpatient	D1	D2	D3	D4	D6	D8	D10	D12	W1-2	W4-6	D30	D90
Demographics	X														
Medical History / Comorbidities	X														
Surgical Details		X													
Discharge (LOS, disposition)			X												
Track Readmission / Reoperation														X	X
Track ED visits, office visits														X	X
Track calls and on-call pages														X	X
Adverse Events		X	X											X	X
Postop Check-in Check-up				X	X	X	X	X	X	X	X				
Recovery Goals												X	X		
HOOS Jr / KOOS Jr	X														X
Promise 10	X														X
Patient Satisfaction (VAS and PPE-15)														X	X
Provider Satisfaction (5-point Likert)															X

4.5 Data Analysis Plan

The difference in percent of respondents indicating a problem on the PPE-15 between treatment and control groups will be calculated as [percent of standard of care respondents reporting a problem, averaged across all PPE-15 domains] – [percent of JointCOACH respondents reporting a problem, averaged across all PPE-15 domains], such that a positive difference indicates that the JointCOACH group was more satisfied than the standard of care group, while a negative value indicates the opposite. A superiority hypothesis test using the two-independent sample t-test will be used to statistically evaluate the difference in the average satisfaction between groups.

5. References

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6. Appendix

6.1 Study Metrics

Metric	Justification
Patient Reported satisfaction – VAS and PPE-15	-Substantial opportunity for the Cleveland Clinic to differentiate itself among health systems and enhance revenue associated with patient satisfaction measures
Patient utilization and compliance	- Substantial opportunity for national exposure as related to national directives to drive patient engagement (See NCQA's Leadership Series: Focus on Patient Engagement at http://www.qualityprofiles.org/leadership_series/patient _engagement/index_patient_engagement.asp)
Physician and staff satisfaction	- Opportunity to demonstrate clinical adoption rates and low barriers to implementation.
Total 90 day post-operative cost from index date+1 (same day) or from index date + LOS (inpatient)* *Claims submitted within 90 days must be limited to ICD-10 listed below (or if hospitalization due to ICD-10 below) in order to exclude unrelated claims.	Joint Coach templates should be able to either *prevent* the complication, or through early detection at the clinic level, reduce expense through minimized emergency room visits and readmissions.
30 day post-op hospitalization rate (this is a readmission if initially an inpatient procedure, or an admission if initially an outpatient procedure)* *Must be associated with ICD-10s listed below in order to exclude unrelated readmissions.	
30-day ED Visit Rate* *Must be associated with ICD-10s listed below in order to exclude unrelated ED visits.	
Number of follow up visits within 90 days	Demonstration to physicians and practices the potential to improve throughput and workflow efficiency by minimizing the number of follow up visits required.
Potentially preventable readmissions and complications identified using JointCOACH	Potentially preventable admissions, events, ED visits. Using an approach similar to 3M's Potentially Preventable Events grouping software, we will examine all events (ED visits, admissions, complications) for relation to index event, and compare this rate to prior year. Data may be supplemented by Physician survey. http://solutions.3m.com/wps/portal/3M/en_US/Health-Information-Systems/HIS/Products-and-Services/Products-List-A-Z/PPR-and-PPC-Grouping-Software/

6.2 ICD-10 codes for relevant metrics

Description 1. Must be in 1st or 2nd diagnosis and must not be chronic, or 2. If patient is admitted, must be in 1st or 2nd diagnosis on hospital discharge.	ICD-10
Infection and inflammatory reaction due to internal prosthetic device, implant, and graft • Due to unspecified implant, device, and graft • Due to internal joint prosthesis • Due to other internal orthopedic device, implant and graft	T8579XA T8450XA T8460XA
Other complications of internal prosthetic device, implant, and graft • Due to unspecified implant, device, and graft • Due to internal joint prosthesis • Due to other internal orthopedic device, implant, and graft	T859XXA T8481XA- T8486XA; T8489XA; T849XXA
Postoperative infection • Other post-operative infection (abscess, septicemia)	K6811 T814XXA
Disruption of wound • Dehiscence of operation wound	T8130XA- T8132XA
Infections of Skin and Subcutaneous Tissue • Upper arm and forearm • Leg except foot • Abscess NOS, Cellulitis NOS	LO3119 LO3129 LO390 LO391
Gastrointestinal hemorrhage • Hematemesis • Melena • Hemorrhage of gastrointestinal tract, unspecified	K920 K921 K922
Hemorrhage NOS	R58
Venous embolism and thrombosis of deep vessels of lower extremity • Of unspecified site	I82409 I8291
Pulmonary embolism and infarction	I2690 I2692 I2699 T82817A, T82818A
Since ED coding is often not as precise as the above, we will likely need to also have these below	
Fever unspecified	R502 R509 R5081- R5094 R6883
Systemic inflammatory response syndrome due to infectious process without acute organ dysfunction	A419
Severe sepsis	R6520
Joint Replacement DRGs	461-462, 469-470
Hip and Knee specific DRGs	466-468, 488-489

6.3 Success Thresholds for Study Metrics

Metric	Threshold	Rationale
Patient reported () satisfaction	≥ 70% satisfied or very satisfied	Value is consistent with most of the Medicare value based purchasing programs. 70% also exceeds thresholds targeted by several other large health systems.
Patient engagement	≥ 70% of members are ≥ 60% engaged with the Joint Coach software	
Physician satisfaction	> 80% physician satisfaction	
Total 90 day post-operative cost (claims submitted) from index date+1 (same day) or from index date + LOS (inpatient)	No increase in cost during pilot study relative to cost averaged across 3 prior years (costs to be adjusted for inflation using either the medical care component of the Bureau of Labor Statistics Consumer Price Index, or The health system internal inflation index if available.)	Standard inflationary cost adjustment in medical economics is the medical care component of the CPI, or using a 3% discount rate.
30-day post-op hospitalization rate	< 4% considering the UHC national average	
30-day ED visit rate		
Number of follow up visits within 90 days		
Potentially preventable admissions		

Provider Satisfaction Survey

What is your role?

☐ Surgeon   ☐ Physician Assistant   ☐ Nurse

How satisfied are you with the use of JointCOACH?

☐ Very Dissatisfied   ☐ Dissatisfied   ☐ Neutral   ☐ Satisfied   ☐ Very Satisfied

How likely are you to recommend JointCOACH to others?

☐ Very Unlikely   ☐ Unlikely   ☐ Neutral   ☐ Likely   ☐ Very Likely