Improvement of Patient Satisfaction and Overall Outcomes Using HealthLoop

NCT03481595

07/30/2019

Introduction and Background:

The Problem

- **Health systems invest significant resources in their efforts to improve quality and reduce costs. The patient is often left out of this equation.**

- **Studies have shown that when patients are engaged, they take increased responsibility for their own health, and play more active roles in prevention.**

- **Because physicians have strong relationships with their patients, they are in the best position to encourage patient engagement. However, physicians need frictionless tools with minimal implementation barriers in order to facilitate this relationship during follow-up.**

Patient engagement has been referred to as the next blockbuster drug, and increasing evidence demonstrates that highly engaged patients experience improved outcomes as well as reductions in complications, readmissions, and total costs of care than patients who are not actively involved in his/her care. While these engagement-related outcomes have been shown in primary care, preventive care, and mental health specialties, relatively little has been done to explore this relationship in orthopedics. An estimated $1.5 billion is spent annually in the US on readmissions following orthopaedic procedures, highlighting the opportunity to impact and improve orthopaedic outcomes. While some readmissions are planned and/or unavoidable, many can be attributed to patient health status, poor discharge planning, and non-optimized care coordination.

GetWell Loop is a SaaS platform that allows physicians to monitor signs and symptoms, and communicate with patients during the postoperative recovery process. The platform enables doctors to identify patients at risk of decline in the follow up period. Patients are engaged through mobile and web-based surveys, reminders, and information personalized to the patient's specific condition or treatment plan. The company's platform also collects patients' feedbacks and monitors status against expected progress. Alerts are sent to physicians or providers about patients who are at risk of treatment failures, complications, or hospital readmissions. Physicians are informed if patients are trending toward an adverse outcome based on the patient's responses. Along with helping to prevent readmissions, GetWell Loop can also help institutions collect patient-reported outcomes (PROs) data, which can be used to evaluate and improve quality measures.

GetWell Loop and the Cleveland Clinic are interested in collaborating on a clinical pilot study to demonstrate that high patient engagement leads to enhanced pre-operative preparation potentially reducing length of stay (LOS), readmissions / reoperations, discharge disposition to home rather than another facility, reduced need for in-person follow up, increased patient (and provider) satisfaction, and increased satisfaction survey completion rates after elective primary hip and knee arthroplasty (THA and TKA). These improvements can translate on higher financial savings through the episode especially in light of the alternative payment models.

Specific Aims: GetWell Loop is currently used by orthopedic groups around the country, and is believed to improve peri-operative outcomes after THA and TKA and mitigate 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 post-operative reporting directly to the clinical team, and 4.

Detecting impending post-operative complications early, enabling timely intervention and preventing avoidable complications and readmissions.

The specific aims of this proposal are to:

1. **Measure the impact of using GetWell Loop on patient (and provider) satisfaction**
2. **Understand the degree to which high post-operative engagement reduces the need for in-person or telephone follow up appointment time**
    a. **Does the use of GetWell Loop lead to fewer potentially avoidable healthcare utilization encounters such as Emergency Department and hospital visits (including readmissions and reoperations)?**
    b. **Does utilizing GetWell Loop improve clinical workflow by minimizing telephone calls and thereby offloading support staff, allowing them to be more efficient?**
    c. **Does utilizing GetWell Loop 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 GetWell Loop allow the practice to identify patients whose in-person follow up needs are minimal, thereby freeing new referrals slots and enhancing same-day access?**
    e. **Does GetWell Loop improve the throughput of patients by eliminating unnecessary follow-up appointments?**
3. **Measure length of stay, discharge disposition (home versus extended care facility) and 90 days readmission and reoperation rates**
    a. **Does the early detection of adverse signs/symptoms that develop between clinical encounters result in earlier intervention that thereby reduces readmission and reoperations?**
    b. **Do Patient Reported Outcomes (PROs), collected at intervals between clinical encounters, provide useful information which facilitates the detections of post-acute complications prior to the next clinical encounter?**
    c. **Does patient adherence to instructions as well as recommended activity levels, captured through continuous activity monitoring such as the Jawbone Up Band (a wristband capable of measuring activity), predict time to recovery, functional outcomes, and potential failure rates? (optional)**
4. **Evaluate the financial impact of GetWell Loop in the episode of care**

Methods: The study design is a prospective randomized trial in which patients undergoing selected hip and knee orthopedic procedures will be offered peri-operative use of GetWell Loop vs standard care. Approximately 300 patients will be enrolled (150 in each group).

Phase 1: 6 month run-in with 9 month follow (total of 12 month long study). Will collect the following outcome measures:

- Demographics (Age, gender, BMI)
- Comorbidities
- Surgery details (Length of surgery, laterality, surgeon)
- LOS and discharge disposition
- Number/length of follow up visits within 90 days (in person and telephone)
- 90 days readmission and reoperations
- Patient and provider satisfaction survey completion rates
- Patient satisfaction (VAS scale and PPE-15)

Phase 2: 3 months for statistical analysis and writing manuscript.

Study Participants

A. Patients – Total Hip and Total Knee Arthroplasty patients treated at Avon Hospital
    a. Inclusion criteria
        i. Primary THA or TKA patient
        ii. Personal consent to participate
        iii. Have internet access or mobile access with a valid email address at the time of enrollment
        iv. Above the age of 18 and are capable of consent
        v. English speaking patient
    b. Exclusion criteria
        i. Staged arthroplasty procedure within 6 months of the index procedure
        ii. Abandoned email address of record (e.g. bounce of email from clinic). If so, then data may be censored in the pilot analysis
        iii. Less than 14 days until scheduled surgery

iv. Outpatient surgery

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 GetWell Loop respondents reporting a problem, averaged across all PPE-15 domains], such that a positive difference indicates that the GetWell Loop 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. All other outcomes will be analyzed using chi-square tests for categorical variables and t-tests for continuous variables. Regression analysis will be conducted for multivariate analysis.

Schedule of Events

Evaluation	**History / PreOp**	**IntraOp**	**90 days postop (Chart Review)**	**90 days postop (survey)**	**1 year (study completion)**
Demographics	X				
Medical History/Comorbidities	X				
Surgical Details		X			
Discharge (LOS, disposition)			X		
Track Readmission/Reoperation				X	
Track ED visits, office visits				X	
Track calls and on-call pages				X	
Adverse Events			X	X	
Patient Satisfaction VAS and PPE-15				X	
Provider Satisfaction Survey					X

Study Metrics

Metric	Justification
Patient satisfaction VAS and PPE-15 (attached)	-Substantial opportunity for the Cleveland Clinic to differentiate itself among health systems and enhance revenue associated with patient satisfaction measures
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-10s listed below (or to hospitalization due to ICD-10s below) in order to exclude unrelated claims.	GetWell Loop 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.
90 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.	
90-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	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/

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