



**Reflexion Health** 

# The VERITAS Trial Verification of Verification at the Intersection of Evidence, Implementation and Policy

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FROM THOUGHT LEADERSHIP TO CLINICAL PRACTICE

### Authors and Disclosures

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### Total Knee Arthroplasty / Replacement (TKA / TKR)



- 700,000 TKRs in the US in 2010<sup>1</sup>
  - Expected to  $\uparrow$  to 3.48 million/year by 2030
- Surgery indicated for:
  - Disability
  - Pain
  - Limited function from osteoarthritis, rheumatoid arthritis, or other deformity
  - Failure to substantially improve with conservative treatments
- Physical therapy (PT) is important to recovery following surgery





Virtual Exercise Rehabilitation In-home Therapy: A randomized Study

To compare the effects of physical therapy-supported virtual exercise versus traditional home and/or clinic-based physical therapy (PT) after total knee replacement (TKR) on:

90-day health service use costs

Patient-centered outcomes

Differential improvement from 6 weeks to 3 months, and how these vary by patient characteristics

ClinicalTrials.gov Identifier: NCT02914210





## POLICY

**Comprehensive Care for Joint Replacement (CJR)** payment model became mandatory for 791 hospitals in 67 geographic areas April 2016 – December 2020

 hospitals accountable for all Medicare FFS Part A and B costs of care during the hospital stay as well as Medicare costs for 90 days post hospital discharge

→ Scaled Back: November 2017, 67 mandatory geographic regions to 34 mandatory regions

## **EVIDENCE**

- CJR bundled payment program implementation that reported <u>substantial hospital</u> <u>savings</u>
- Decreases in post-acute care only occurred when it was purposely included and addressed in the bundle





## POLICY

### **Post-acute care**

( = acute rehabilitation, skilled nursing rehab/stay, home health, outpatient clinic therapy) is the single largest driver in the variation of Medicare spending

## EVIDENCE

 Some form of supervised therapy with an exercise program between visits supports best postsurgical outcomes

→ Payment Reform Needed

### PTs Per 1000 People

80-100th percentile 60-80th percentile 40-60th percentile 20-40th percentile 0-20th percentile

Center for Connected Health Policy found most states currently have established telehealth policies for primary care providers that often do not include physical or occupational therapists

## **Reality of Post-acute Rehab for TKR**

Supply & Demand

### Challenges

Variation: dose & duration

Insurance Coverage

Geographic

Access

**Out of Pocket \$** 

Adherence



## Digital Technology for Rehabilitation

- Level 1 = e-health: Online, virtual and avatar-based instructional programs; visual and audible instructions
- Level 2 = telehealth: Telerehabilitation allows for communication between patient and physical therapist in real time
- Level 3 = wearables/motion sensing: Asynchronous remote monitoring and feedback on performance
- Opportunity of levels 1-3 together: increase access and support larger number of patients



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### Enrollment Centers Within a 50-mile Radius



## Study Timeline









## Eligibility Criteria

### Inclusion

- ≥ 18 years of age
- Scheduled to have non-traumatic knee replacement
- Enrolled a minimum of 2 weeks prior to surgery (in-person visit)
- Have a Risk Assessment and Prediction Tool (RAPT) score of
   ≥ 6 indicating expected discharge home after surgical hospitalization

### Exclusion

- Unable or unwilling to provide informed consent (no barriers to comprehension)
- Scheduled for staged bilateral TKR
- Living in a nursing home prior to surgery



### Tele-Rehab Supported PT

Patients randomized to VERA will:

Have VERA installed at home

Undergo prehab with study PT on VERA system

**Receive In-hospital Care** 

Undergo post-op rehab using VERA at home, monitored remotely by study PT

Complete standard post-op follow-up visit with surgeon

### Traditional Clinic/HH PT

Patients randomized to traditional PT will:

Undergo prehab as prescribed by surgeon

**Receive In-hospital Care** 

Undergo post-op rehab using home health or clinic PT

Complete standard post-op follow-up visit with surgeon



### VERA



PATIENT INTERFACE

- Digital prescription fulfillment
- Skeletal and joint tracking
- Patient education and real-time feedback
- Longitudinal functional assessments
- Tele-Health Video Conferencing

#### CLINICIAN INTERFACE



- Create protocols
- Personalize exercises
- Remotely monitor patient
   progress
- Review patient videos (exception basis)
- Tele-visit when needed







## **Randomization by Site**

	Site 01	Site 02	Site 04	Site 05
Total # of patients by site	36	144	46	80
Number of site months	15	18	17.1	15.3
Average/month	2.4	8	2.7	5.2





## WHAT DID WE FIND?





### Intervention Patients Had Lower Costs

### **Intervention Group**

Average (SD) 12 Week Cost = \$1781.96 (2531.77)

Median: \$1050.00

(Range: \$600.00-17500.00

### **Usual Care**

Average (SD) 12 Week Cost = \$4526.77 (4498.35)

Median: \$2805.00

Range: \$0-27913.00

### 60% Lower Billable Costs





### Where did the costs come from?

Secondary Outcome	Virtual PT (n=143)	Usual Care (n=144)	P-value
12-week Healthcare Utilization			
Total [mean (SD)			
Home Health Visits	36 [0.3 (1.6)]	686 [4.8 (6.3)]	- <.001
Outpatient Physical Therapy	199 [1.4 (4.4)]	1450 [10.1 (8.1)] 🔶	- <.001
*Calls/emails to Physical Therapy	817 [5.7 (5.2)]	19 [0.1 (0.4)]	<.001
MD Clinic Visits	379 [2.7 (1.7)]	398 [2.8 (2.0)]	NS
*Call/emails to MD	149 [1.0 (2.0)]	126 [0.9 (1.8)]	NS
Urgent Care	11 [0.1 (0.3)]	16 [0.1 (0.4)]	NS
Emergency Room	10 [0.1 (0.3)]	14 [0.1 (0.3)]	NS
Inpatient Rehabilitation Stay	0 [0 (0)]	2 [0 (0.1)]	•
Skilled Nursing Facility Stay	2 [0 (0.1)]	5 [0 (0.2)]	NS
Rehospitalization	12 [0.1 (0.3)]	30 [0.2 (0.5)]	- 0.007



## **Outcomes of Interest**

- Costs
- Health service use
- Range of motion
- Gait speed
- Pain
- Falls

- KOOS
- PROMIS
- Satisfaction with Physical Function
- Physical activity
- Return to work





## **Non-inferiority**

Aims to demonstrate that Vera is not worse than the usual care by more than a small pre-specified amount.

- Effectiveness hypothesis: The tele-rehab intervention is non-inferior to traditional PT (KOOS, Range of Motion, Walking Speed)
- Safety hypothesis: Tele-rehab intervention is noninferior to traditional PT for pain and rehospitalization.
  - We fail to conclude that the tele-rehab intervention is noninferior to traditional PT for experiencing a fall after hospital discharge





# Did Vera patients report more days of therapy? Participate as prescribed!

YES! and Yes!

VERA: Avg of 5.9 days / week (SD 1.7), 88.3% completed all Usual Care: 3.3 days per week (SD 2.0), 65.4% completed all

p<0.001

Reasons for not completing exercises as prescribed were similar between groups





### Did people like it?







# How do we \$cale this?

## Policies that Can Change the Landscape

### Organization

**Bundled Payments** 

- ↓ cost but no difn in quality measures
- ↓ cost due to <</li>
   inpatient PAC &
   no changes to
   referral or
   provider quality

### **PT Providers**

Tech-enabled Services

and Virtual Encounters

- ✓ 28 states have
   either laws or boards
- Geographic and pop. limits
- "Qualified Health Care Professional"

### Individual

Costs, Costs, Access

- Copayments
- Consent
- Convenience





### Implementation Considerations to Scale

Reach	<ul> <li>Consider adopter:innovation characteristics</li> <li>Policies for reach across state lines</li> </ul>
Effectiveness	<ul><li>PT supported use of technology</li><li>Evidence for multiple components, not just 1</li></ul>
Adoption	<ul> <li>Payor</li> <li>Provider (Systems and/or Individual Providers)</li> </ul>
Implementation	<ul><li>In-person visits: when, how many, how often</li><li>Hub or spoke</li></ul>
Maintenance	<ul><li>PT turnover</li><li>Support for longer-term behavior change</li></ul>





## **Summary**

- Virtual PT with PT support should be used to expand access to rehab
- It saves total costs, prevents readmissions, improves mobility
- Policies for telehealth need to include therapists



