NCT03653455

Patient Outcomes Collection: How can we do better? A Randomized Trial to Determine Factors Which May Affect Patient Compliance.

09/27/2022

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PI: Nikhil Verma, MD

Purpose:

The purpose of this study is to identify factors that will increase completion rates of post-operative patient reported outcome surveys (PROs). Specifically, we will compare completion rates of PRO surveys from three groups of participants. Group one (Arm 1) will receive no pre-operative or post-operative PRO instruction, Group 2 (Arm 2) will receive PRO instruction pre-operatively and 6 month post-operatively and Group 3 (Arm 3) will receive low-value monetary incentives for completion of their 6 month and 1 year PRO surveys. This group will receive no pre-operative or post-operative PRO instruction.

Background and Significance:

Patient reported outcome surveys (PROs) are widely used by clinical providers as important tools to help inform their clinical and research practice, and to improve quality of care for patients. In addition, PROs are increasingly cited as a tool in measuring surgical performance and the value of health care services being delivered. The Center for Medicare and Medicaid Services (CMS) is intending to adopt an expanding array of PROs to help determine physician reimbursement rates. In the field of orthopedic surgery, PROs are routinely used to help surgeons deliver quality care to patients and to demonstrate the value of such care to payors and other stakeholders[8, 9].

For PROs to adequately and reliably assess the success of a medical intervention, it is imperative that the data collected accurately represent the entire patient cohort and how they respond to a given treatment. The failure to do so increases the risk of collecting data that are biased or skewed, and may misrepresent the outcomes of the entire cohort. For example, patients who do not complete their surveys may be younger with better clinical outcomes. Factors such as age, language, socioeconomic status and technological literacy can adversely affect patient response rates. Alternatively, patients who are undergoing prolonged care due to poor outcome or complication may be more likely to complete post-operative outcomes. These forms of selection bias can significantly impact the validity of the scores.

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In the absence of high response rates, such results might falsely lead to the conclusion that responders must therefore be older and sicker, or have experienced a complication. To mitigate the effects of such bias, higher response rates must be achieved.[10] The rate at which patients complete and return surveys (response or compliance rate) is widely used to evaluate the quality of survey data[11], both pre-and post-operatively. This, in turn, decreases confidence in validity and interpretation of results[11].

The utility and quality of data captured by PROs is largely dependent on patients' response rates, both pre- and post-operatively. For pre-operative surveys, higher response rates may be achieved if patients are reminded to complete their surveys at an office visit or prior to surgery. However, patient non-compliance presents a major challenge post-operatively, undermining PRO data integrity.[1-3]

To help with PRO response rate compliance, electronic and web-based platforms have been used successfully, and effectively, to administer and collect PRO data.[2] Automating PRO administration saved time for patients and providers in the office, post-operative compliance rates remained low in this study. According to another study, electronic (as opposed to paper) administration of PROs only modestly improved follow-up compliance rates[14]. In an attempt to improve response rates, efforts have been made to reduce patient burden (by reducing the number of questions asked, for example), to regularly remind patients to complete their forms (either by email or telephone), or even offer patients monetary or non-monetary incentives.[2-5] A comprehensive review of literature conducted by Edwards *et al.* showed that patients were more likely to complete their surveys if they were offered monetary incentives[4].

Study Hypothesis:

We hypothesize that participant PRO instruction and low-value monetary incentives will result in an increase PRO completion rates.

Study Design and Subject Selection:

This is a prospective, comparative cohort study comparing how active participant engagement through PRO instruction and education or monetary incentives may improve PRO compliance. These PRO compliance rates

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will be compared with participants that receive no PRO instruction and education or monetary incentives to complete PRO surveys.

The participants will be recruited from 5 practices at Midwest Orthopedics at Rush, and enrollment is expected to be completed 1 year after the initiation of the study.

Inclusion Criteria:

Patients scheduled to undergo shoulder arthroscopy for rotator cuff condition (sub-acromial decompression, distal clavicle resection, biceps tenodesis, partial or full thickness rotator cuff tear repair or debridement) will be eligible for enrollment in the appropriate cohort. There will be no restrictions to this enrollment apart from that presented in the exclusions below.

Exclusion Criteria:

1. Minors or those over the age of 80
2. Subjects lacking English proficiency to complete the PROs of interest.
3. Past or current medical history that would preclude patients from undergoing surgery.

Consent process:

Potential participants will be identified by medical chart review and eligibility requirements. Study staff will call potential participants to inform them about the study and invite them to participate. The potential participant must be made fully aware of the protocol requirements and s/he must acknowledge his/her understanding and agreement prior to signing the informed consent.

Informed consent will be obtained via eConsent through potential subject email via Rush approved, secured electronic platform, Patient IQ. Once the participant has consented, a study staff member will call the participant to schedule their study visit.

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During the consent process, patients will be notified that we are evaluating outcomes collection. However, an in depth discussion of randomization and collection of compliance data will be avoided in an attempt to avoid bias in results.

Using an internet-based random number generator, consented participants will be block-randomized to avoid substantial imbalances in the number of patients assigned to each group. There will be 33 patients per study arm, with a final allocation ratio of 1:1:1.

Participants will be randomized to one of 3 groups: Group one (Arm 1) will receive no pre-operative or post-operative PRO instruction or education, Group 2 (Arm 2) will receive PRO instruction/education pre-operatively and 6 month post-operatively and Group 3 (Arm 3) will receive low-value monetary incentives in the form of 3-10$ Amazon gift cards. One gift card will be given to participants in Group 3 (Arm 3) after verified completion of their preoperative, 6-month and 12-month PRO surveys, respectively. The gift cards will be sent to the participant's home address after the survey is verified completed in Patient IQ. Group 3 (Arm3) participants will receive no pre-operative or post-operative PRO instruction/education to complete their PRO surveys.

Study Endpoints:

Primary Endpoint:

The primary endpoint will measure whether patient engagement affects PRO compliance. Specifically, compliance will be measured for the PROs listed below at preoperatively, as well as 6 months and 1-year post shoulder arthroplasty:

- American Shoulder and Elbow Surgeons (ASES) Shoulder Assessment Form
- Single Assessment Numeric Evaluation Score (SANE)
- Veterans Rand (VR)/Short Form (SF)-12

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Secondary Endpoint:

- Assess what effects age, English proficiency, and technological literacy have on PRO compliance. Patients will be asked to complete a short custom survey (Appendix 2), administered via Patient IQ, to help measure how the above-mentioned factors might affect compliance rate.
- Assess what effect the length of survey and time will have on compliance rate.

Study Interventions

Group 1 (Arm 1)

33 patients undergoing arthroscopic shoulder surgery will be randomly chosen to receive a set of PROs through an electronic data collection system (Patient IQ), and will be asked to complete their forms prior to surgery, as well as at 6-months and 1-year after surgery. We will administer a short form (Appendix 2), just once at the start of the study to help assess whether language, age, and/or technological literacy might affect compliance. No additional contact by clinical or research staff will be made with Group 1 (Arm 1) participants for post-operative form collection.

Group 2 (Arm 2)

33 patients undergoing arthroscopic shoulder surgery will be randomly chosen to have a discussion with the physician or physician assistant regarding what PROs are, and how they can help both the patient and physician make informed decisions about a specific medical intervention. A checklist of discussion points will be available to providers to ensure all key elements are reviewed with patients (see appendix 1). This discussion will be included at the time of surgical scheduling, alongside other routine discussion points such as informed consent process, surgical scheduling information, and peri-operative instructions.

Participants will be assigned a set of PROs through an electronic data collection system (Patient IQ), and will be asked to complete their forms prior to surgery, as well as at 6-months and 1-year after surgery. In addition, we will ask patients to complete a short form (Appendix 2), just once at the start of the study to help assess whether language, age, and/or technological literacy might affect compliance.

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Group 3 (Arm 3)

33 randomly selected participants undergoing arthroscopic shoulder surgery will be assigned PROs through Patient IQ. They will be asked to complete their forms prior to surgery, as well as at 6-months and 1-year after surgery. We will administer a short form (Appendix 2), just once at the start of the study to help assess whether language, age, and/or technological literacy might affect compliance. Participants in Group 3 (Arm 3) will be told they will receive a $10 Amazon gift card if they complete their pre-operative forms, a $10 Amazon gift card if they complete their forms 6-months post surgery, and a $10 Amazon gift card if they complete their forms 1-year post surgery. The gift card will be sent to the participant's home address after the survey is verified completed in Patient IQ.

For all Groups, we will monitor the patient compliance rate for the following questionnaires: ASES shoulder assessment form, Single Assessment Numeric Evaluation (SANE), and VR/SF12. All groups will be asked to respond to the short form (Appendix 2), just once at the start of the study to help assess whether language, age, and/or technological literacy might affect compliance.

Automatic email reminders will be sent to patients every 5 days, starting 60 days before forms expire until the forms are completed.

Participant compliance will be documented at preoperatively, 6 months and 1-year post shoulder arthroplasty.

Data analysis:

We anticipate that patient education, as well as providing low-value monetary incentives, will overall enhance patient participation and that these strategies will increase post-operative survey completion and rate of return. We further predict that patient education may have an equal or more significant impact on patient compliance to financial compensation, and avoid additional expenditure. We will monitor patient compliance using tools available in Patient IQ, which, allow determination of form completion for each patient.

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Based on our statistical power analysis using a chi-squared test of proportions, we plan to enroll 100 patients per study arm. This is sufficient to show a difference of 20% in the PRO completion rate with a beta of 0.80 and an alpha of 0.05. As historical research data analytics have noted that a 70% response rate is required to minimize potential forms of bias in report results of a given procedure, we believe a 20% increase in response rate is reasonable to assess whether it is possible to reach the 70% threshold.

While we expect response rates to increase in the treatment (patient engagement plus email reminders) vs. control (email reminders only) groups, it is possible that we might not observe a statistically significant difference among our treatment groups. This notwithstanding, our data will help provide important information as to which strategy might be more pragmatic to ensue.

Long Term Aims:

Given the increasing importance of PROs in both clinical practice and research, and concerns overpatient compliance, we believe the proposed research will enhance our understanding of strategies that may be employed to increase response rates and, hence, data quality. Long term, the information gained in this proposal will help set realistic expectations and benchmarks in the orthopedic community in regard to PRO administration, data collection, and patient compliance rates.

Risks and Benefits:

The risk to the subject for participating in this study is loss of patient confidentiality. To minimize this risk, data will be kept on a secure, password-protected server at Midwest Orthopedics at Rush University Medical Center.

There is no direct benefit to the participant. The benefit is to identify factors that will increase completion rates of post-operative patient reported outcome surveys (PROs) in order to improve patient care.

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Data & safety monitoring:

There is minimal risk to the participants except for the potential for loss of privacy and confidentiality, but every reasonable effort will be made to protect the patient's information while their data is used as part of this study.

Data storage & confidentiality:

The data is maintained on a secure at Midwest Orthopedics at Rush and Patient IQ. Participants' identities will be coded via the use of a separate key Excel document correlating participants' medical record numbers with a study ID assigned for the sole purpose of this study.

Upon publishing of the study's results, study data held on the excel spreadsheet and data key will be securely deleted from the Midwest Orthopedics at Rush computer. No social security numbers, names, addresses, phone numbers, or other personal information beyond what is mentioned in this submission will be recorded. Files will not be shared with non-study personnel. Any presentations or publications that result from this study will not identify any participants individually and may present the data results in an aggregated form.

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Appendix 1

Discussion points:

- What are Patient Reported Outcome Forms?
  - *Clinician's perspective*
    - help gauge patient's progress with respect to normative data for the same procedure
    - use as a research tool
    - help patients like *you*!
  - *Patient's perspective*
    - help gauge patient's progress with respect to normative data for the same procedure
    - Identify patients at risk for poor outcome early
    - use as a research tool
    - help patients like *me*!
- Why are you (the patient) being asked to complete these forms?
  - utility
  - generalizability
- Do these forms directly affect you (the patient)?
- Do you (the patient) have any questions or concerns?

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Appendix 2

Custom Survey

1) How old are you?

- 18-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65+

2) What is your primary language?

- English
- Spanish
- Other (please specify) ----------

3) How comfortable do you feel using a computer or a smart device (for example an iPad, smart phone, etc)?

- Very comfortable
- Somewhat comfortable
- Not at all comfortable