STUDY PROTOCOL

Study name	Understanding Non-Response in Spine Fusion Surgery
Principal investigator	Dave Flum, MD, MPH
Project lead	Amy Cizik, PhD, MPH
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ABSTRACT

There is considerable debate about the effectiveness of spine fusion surgery for degenerative disc disease (DDD) and other diagnoses related to chronic back pain. As many as 1-in-3 patients who undergo spine fusion do not report improvements in pain or functional status. Additionally, there are currently no evidence-based selection criteria to help surgeons determine which patients will respond to spine fusion surgery and which will not benefit.

The goal of this study was to better understand which patients are more likely to benefit from spinal fusion surgery. The Comparative Effectiveness Research Translation Network (CERTAIN) Spine Fusion Study partnered with spine surgery clinics to invite patients to participate in research activities designed to identify the impact of spine fusion surgery on the outcomes that matter most to patients. As part of this study, patients took surveys before and after their spine fusion surgery, and shared elements of their medical records for review. CERTAIN anticipated that this study would produce a paradigm that clinicians can use with patients to determine whether spine fusion surgery is right for them and identify any modifiable risk factors that may impact their response to surgery.

OBJECTIVE

Determine patient characteristics associated with non-response among patients undergoing lumbar fusion for DDD.

Rationale: *A patient's sense of activation in managing their health, loci of control, tendency towards catastrophizing, social support, satisfaction with work, self-perceived quality of life, expectations, general mental health, anxiety and depression, and extent of critical medication (e.g., opioids, sleeping aids) use have been associated with clinical outcomes and self-perception of health status. These parameters have not been well studied among those who fail to improve with spine surgery compared to responders. Nearly all Spine SCOAP patients undergo baseline and follow up surveys of patient reported measures. We will perform a prospective cohort study adding standardized measures of personality traits and mental health and will evaluate their association with changes in function and pain at six months after surgery.*

DESIGN

Recruitment Workflow Notes

All site specific processes are in *italics*

UWMC and HMC:

- *Patients were identified from surgery schedules* (eligible if: lumbar fusion (L1-S1), over 18, English as primary language, not revision surgery, surgery date in > 10 days (not official study inclusion criteria, but needed to ensure enough time for mailers))
- *Research staff screened each patients EMR to confirm eligibility and noted in EMR disclosure log*

- Research staff sent each eligible patient a recruitment mailer containing: consent form (2), HIPAA Authorization Form (2), Study Intro Letter, Baseline survey, and a return envelope
- One week after mailer was sent, phone recruitment began; 5 calls over ~10 days
- During phone call: research staff delivered screening questions, reviewed forms, outlined which were copies for patient's own records and which to return, gave instructions on how to return
- Patient was enrolled when consent and baseline were returned via mail (HIPAA form return did not impact enrollment)

Proliance:

- Patients were identified from an automated feed delivered from Proliance IT via secure email once a week* (eligible if: lumbar fusion (L1-S1), over 18, English as primary language, not revision surgery, surgery date in > 10 days (not official study inclusion criteria, but needed to ensure enough time for mailers))
- *Research staff screened schedule for potentially eligible procedures and noted in EMR disclosure log, even though Proliance EMR was not accessed at this time*
- Research staff sent each eligible patient a recruitment mailer containing: consent form (2), HIPAA Authorization Form (2), Study Intro Letter, Baseline survey, and a return envelope
- One week after mailer was sent, phone recruitment began; 5 calls over ~10 days
- During phone call: research staff delivered screening questions, reviewed forms, outlined which were copies for patient's own records and which to return, gave instructions on how to return
- Patient was enrolled when consent and baseline were returned via mail (HIPAA form return did not impact enrollment)

Evergreen Health:

- *Patients were identified by clinic staff* (eligible if: lumbar fusion (L1-S1), over 18, English as primary language, not revision surgery, surgery date in > 10 days (not official study inclusion criteria, but needed to ensure enough time for mailers))
- *Clinic staff screened and consented each patient in-person, and completed screening survey in Microsoft Forms to alert UW staff afterward*
- *If patient needed further outreach, UW research staff did phone outreach to complete forms, and sent recruitment mailer if needed* Mailer containing: consent form (2), HIPAA Authorization Form (2), Study Intro Letter, Baseline survey, and a return envelope
- One week after mailer was sent, phone recruitment began; 5 calls over ~10 days *if needed*
- During phone call: research staff delivered screening questions, reviewed forms, outlined which were copies for patient's own records and which to return, gave instructions on how to return *if needed*
- Patient was enrolled when consent and baseline were returned *from Evergreen; or via mail from patient directly* (HIPAA form return did not impact enrollment)

Original Recruitment Design

As designed in the original grant, Spine Fusion study was intended to be a research study built on top of a QI initiative (CERTAIN). The original plan was to tack the SF screening, consent, and if time allowed, baseline on to the end of the CERTAIN baseline that was implemented in several clinics at the time of

study start. This was meant to result in a nearly seamless process of QI data collection and study enrollment for eligible patients. Unfortunately, the implementation of CERTAIN did not allow for this workflow to come to fruition successfully.

Barriers:

- Tablets: Original grant depended on patients completing CERTAIN baseline for themselves via tablet in clinic waiting room, however, patients and staff had technical difficulty with tablets
- Time: not enough time in waiting room or during rooming process to complete the CERTAIN baseline, let alone SF screening and recruitment
- Variability: each CERTAIN clinical site implemented CERTAIN at a slightly different point in their workflow (i.e. in waiting room, after rooming, after surgery scheduling, etc.) which made it difficult to provide clinic staff with guidance about how to assist with enrollment
- QI vs. Research: by not classifying SF as a multi-site study with "engaged" sites, the flexibility to allow clinic staff to actively enroll patients was lost (the exception to this is Evergreen, who had separate IRB approval for a research-only approach to enrollment, not QI)

Data Collection Design

A combination of Quality Improvement (QI) databases and research databases were used to complete the final dataset for this study. Most hospitals in Washington (WA) State participate in a novel, prospective care surveillance initiative called Spine Surgical Care and Outcomes Assessment Program (Spine SCOAP) that allows benchmarking on the indications for, processes of care, clinical outcomes and changes in patient reported outcomes (PROs) including pain and function for patients undergoing spine surgery. Spine SCOAP's analytic group, the Comparative Effectiveness Research Translation Network (CERTAIN) assesses PROs at 60-90 days, 12 and 24 months. Spine SCOAP data was obtained through CERTAIN, and research data was collected directly from patients via email or mail, rather than in the clinic as originally proposed. These surveys included additional baseline, 60-day, and 1-year characteristics and the outcome measures to the original CERTAIN surveys through the DatStat platform.

Socio-demographic, clinical and procedural characteristics were collected from both Spine SCOAP, the CERTAIN QI surveys, and the additional research measures. Spine SCOAP data included age, zip code, race and ethnicity, insurance type, and employment status. Clinical characteristics included diagnosis and indication for surgery, preoperative comorbid conditions, known preoperative risk factors (e.g. cigarette smoking), laboratory results (e.g., albumin and HbA1c), and current medical treatments (i.e., statin, beta blocker, ACE or ARB inhibitors, therapeutic anticoagulants, steroids, and narcotic pain medication). Surgical approach (i.e. minimally invasive or open and anterior or posterior), perioperative care, fusion technique, instrumentation used and adverse clinical outcomes were also included.

METHODS

Ten CERTAIN clinics agreed to participate in the study, including: Confluence Health, Evergreen Health, Harborview Medical Center (HMC), UW Medical Center (UWMC), and six clinics from Proliance Surgeons. Within these CERTAIN clinics 28 surgeons participated. The sites represented close to 70% of

the Washington SCOAP network, with representation across public, private, and geographic healthcare settings.

INCLUSION CRITERIA:
Patients may enroll in Spine Fusion if they:

- Are receiving care from a spine surgeon at a participating clinic
- Are over 18
- Are fluent in English (able to take surveys via mail, phone, or online)
- Have lower back pain (pain for more than three months, or pain for at least half the days in the past 6 months)
- Are planning to have lumbar spine fusion surgery
- Have no history of previous spine surgery
- Are not a member of a vulnerable population
- Are able and willing to provide informed consent to participate in a research study

EXCLUSION CRITERIA:
Patients may not enroll in Spine Fusion if they:

- Are under 18 years of age
- Do not speak English (are unable to take surveys via mail, phone, or online)
- Do not have lower back pain (pain for less than three months, or not even for half the days in the last six months)
- Are not planning to have lumbar spine fusion surgery
- Have had spine surgery previously
- Are a member of a vulnerable population
- Indicate that they are unable or unwilling to provide informed consent to participate in a research study

For more information regarding the scientific background and statistical methods, see the Statistical Analysis Plan (SAP).

LIKELY IMPACT

This exploratory study is being conducted because the prevalence of these characteristics needs to be determined in order to develop accurate predictive algorithms and risk factors for non-response to lumbar spine fusion surgery. Additionally, the findings of this study will be used to establish a statistical and methodological framework to identify patients at high-risk for non-response, informing both decision makers and future interventions aimed at modifiable factors.