Title: **Shoulder Symptom Irritability Scale: A Single-Blinded Observational Study (SSIS)**

Identifier: **NCT02995941**

Date of Document: **October 31, 2016**

STUDY PROTOCOL with SAP & ICF

Section A: Experimental Design

This study will employ a quasi-experimental design utilizing repeated measures (specific aim 1), followed by cross-sectional analysis (specific aims 2 and 3). The target sample size for the study will be 25 physical therapists and 90 patients. Patient-reported outcome measures were selected based upon their reliability, validity and internationally accepted use. Given that there is no single universal patient reported outcome measure for the shoulder, multiple measures will be utilized during the third aim of this project.

Specific Aim 1

The first specific aim will be to determine the reliability of the shoulder symptom irritability classification scale. To address this aim, the project will analyze paired rater judgments of shoulder symptom irritability (high, moderate or low) from 90 patients with shoulder pain. Raters will be physical therapists from multiple clinics trained in rating shoulder symptom irritability. Prevalence-adjusted, bias-adjusted Kappa for ordinal scales (PABAK-OS)[1] will be the primary measure of reliability. However, analysis may be adjusted based on the data distribution.

Specific Aim 2

The second aim is to compare level of functional limitation between shoulder symptom irritability groups. To address this aim, the project will analyze patient-reported functional measures using analysis of variance with post-hoc analysis to compare functional disability across different levels of shoulder symptom irritability. The independent variable will be the shoulder symptom irritability level, and dependent variables will include patient-reported functional status measures. The hypothesis is that patients with higher irritability will report greater functional deficits.

Specific Aim 3

The final specific aim is to determine if the level of shoulder symptom irritability dictates the chosen intervention intensity. To address this aim, raters will select planned intervention choices for each of the 90 patients, utilizing a pre-specified list of possible physical therapy interventions. Data analysis will include PABAK-OS for correlation, and independent t-test for differences between clinical specialist and non-specialist groups. The hypothesis is that patients with high irritability will be prescribed interventions aimed at minimizing the physical stress to the affected tissue(s), while patients with low irritability will be prescribed interventions at a higher intensity to address the physical impairments.

Section B: Subjects

1. Number of subjects

   Raters will be recruited from outpatient physical therapists in the St. Luke's University Health Network with an expected response of 25. Patient subjects will be recruited from a convenience sample of consecutive patients presenting for physical

therapy consultation for shoulder pain. Expected patient sample size is 90 subjects over a 6-month period. As pilot data has demonstrated K>0.85 with similar methodology,[2] this study is powered at 80% to determine a K>0.80 with a sample size of 48 with a null K value of 0.40.[3] However, due to the expected restriction of subjects in phases 2 and 3 of this study (to only those subjects with 100% agreement between raters to maintain the integrity of internal validity), doubling the required sample size is prudent to maintain power of the subsequent analyses.

2. Criteria for inclusion/exclusion

Rater Group

Inclusion criteria will be state licensure as a physical therapist and regular clinical practice with patients with shoulder disorders, defined as a minimum of 500 clinical hours per year in an orthopaedic setting with >10% of patients with shoulder disorders. **Exclusion criteria** will include not meeting inclusion criteria.

Patient Group

Inclusion criteria will be presenting with a chief complaint of shoulder pain, not extending to the neck, for outpatient physical therapy consultation. **Exclusion criteria** will include illiteracy in English and age less than 18 years. Additionally, subjects will be excluded from the study if they present with pain or symptoms distal to elbow, have had shoulder surgery on the symptomatic side in the past year, if active or passive cervical spine ROM reproduces shoulder pain, have a positive Spurling's test, or if they are unable to complete the patient reported functional questionnaires. Subjects found to have need for referral to another medical professional will be provided with the appropriate referral. If the reason for referral would prevent them from participating safely in the study, that subject will be excluded from testing.

3. Institutional Review Board (IRB) approval

Ethics approval has been obtained from the Institutional Review Boards of St. Luke's University Health Network (SLHN 2016-61) and Nova Southeastern University (2016-379). Written informed consent will be obtained from each subject prior to enrollment.

Section C: Methods and Instrumentation

Instrumentation

Demographic information questionnaire

The survey will collect demographic data from raters including name, age, years of practice, advanced certification(s), gender, entry-level degree, and highest earned degree.

Shoulder Symptom Irritability Classification Scale

Raters will classify patient subjects in one of three shoulder symptom irritability levels based upon: pain level, presence of night or resting pain, onset of pain during motion, differences between active and passive range of motion, and level of disability.[4-6]

Patient-Reported Outcome Scales

Three patient-rated outcome scales will be administered for the purpose of enhancing generalizability, as there is no single gold standard patient-reported outcome scale for patients with shoulder pain.[7,8]

Focus On Therapeutic Outcomes (FOTO)

The FOTO scale[9] is a computerized adaptive test (CAT) and will be administered via iPad (iPad 2, Apple, Cupertino, CA) at each St. Luke's Physical Therapy clinic. The FOTO scale has been found to be a reliable and valid measurement system for outpatient orthopedic rehabilitation,[9-11] and has demonstrated good construct validity and responsiveness for patients with shoulder complaints.[12,13] The FOTO questionnaire has a low burden on patients, with a mean test administration time of 1 minute and 29 seconds (SD = 90 seconds).[12] Furthermore, the standard error of the mean (SEM) has been found to be 1.30 with a minimal detectable change with 95% confidence (MDC_{95}) of 3.60-10.88 functional score units.[12,13] Additionally, FOTO will be utilized to collect demographic data for each patient including comorbidities, age, gender, height, weight, chronicity of symptoms, type of insurance used, level of fear avoidance, and number of surgeries.

Penn Shoulder Score (PSS)

The Penn Shoulder Score (PSS), originally published in 1999[14] and validated in 2006,[15] is a self-report questionnaire consisting of three sections: pain, satisfaction, and function. The function subscale consists of twenty (20) items, each on a 4-point Likert scale. Each item is scored as 0 (can't do at all), 1 (much difficulty), 2 (with some difficulty), or 3 (no difficulty). The item scores are then summed to determine the subscale score out of 60 (no difficulty for all items). Resultant scores for each subscale are divided by the total range from 0-100 with 0 as greatest disability and 100 as no disability.[14] The PSS has demonstrated good test-retest reliability ($ICC_{2,1}$ = 0.94) with a SEM_{90} of 8.5.[15] The MDC_{90} is 12.1, and the minimal clinically important difference (MCID) was found to be 11.4.[15]

American Shoulder and Elbow Surgeons (ASES) Shoulder Score

The American Shoulder and Elbow Surgeons (ASES) Shoulder Score, originally published in 1994[16] and validated in 2002,[17] is a self-report questionnaire consisting of two sections: one visual analog scale (VAS) to

measure pain, and ten items to measure activities of daily living. The questionnaire takes 3 minutes to complete and is scored as follows: [(10 – VAS pain) x 5] + (5/3 x sum of ADL items).[18] Resultant scores for each subscale range from 0-100 with 0 as greatest disability and 100 as no disability.[18] The ASES has demonstrated good to excellent test-retest reliability (ICC = 0.61-0.96) with an SEM of 6.7.[18] The MDC_{95} is 11.2,[17] and the MCID was found to be 12.0.[19] A recent systematic review found the ASES to be one of the only patient-reported functional scales for rotator cuff disease to have measurement error below 10% of the global score.[20]

Numeric Pain Rating Scale

The Numeric Pain Rating Scale (NPRS) is an 11-point Likert scale that can be used to measure pain intensity. The NPRS is a standard pain assessment scale that uses a 0-10 scale (no pain to worst pain imaginable, respectively) in order to determine a patient's level of pain. Patients rate their current level of pain and their worst and least amount of pain in the last 24 hours. The average of the 3 ratings is used to represent the patient's level of pain. The NPRS has demonstrated good reliability ($ICC_{2,1}$=0.74)and responsiveness (MDC = 2.5, MCID = 1.1) in subjects with shoulder pain[21] and excellent reliability in an upper extremity orthopaedic population.[22] Furthermore, the NPRS has been used to assess pain severity of both traumatic and atraumatic etiologies.[23]

Range of Motion

Goniometric measurements of shoulder AROM in symptomatic patients demonstrates fair-good reliability with regards to intra- and inter-rater reliability (Inter-rater Rho = 0.64-0.80; Intra-rater Rho = 0.53-0.91).[24-27] Passive range of motion (PROM) demonstrates even greater reliability with intra-examiner ICC values = 0.98, and inter-examiner ICC values ranging from 0.87-0.89.[25]

End Feel - Pain

The ability to utilize end feel to determine sequence of pain in relation to tissue resistance has generally shown good intra-rater reliability (K = 0.48 to 0.59,[28] K_w = 0.59 to 0.87[29]) and is frequently used for clinical decision-making.[29]

Procedures

At least 2 raters will be recruited from each site. Raters will be trained with the following materials: (1) Collaborative Institutional Training Initiative (CITI) training for those involved in consenting the patients; (2) the reading of the Staged Approach for Rehabilitation Classification: Shoulder Disorders[6] with direction to pay special attention to the section on Level 3 classification and Table 3;[6(pp 795-6)] and (3) a short online narrated presentation to reinforce understanding of the content. The intent of this training method is to increase the generalizability of the study results, and to avoid overly specialized training methods that would be difficult to reproduce clinically.

Patients will be recruited by the raters from their regular caseload (Appendix C). Patients will receive a brief explanation about the study, provide informed consent, and be asked to complete the functional questionnaires as part of the outpatient admissions process. The first therapist will rate the patient's shoulder symptom irritability level during the normal examination process utilizing the intake (Appendix C). Raters will inquire on the presence of night or resting pain and complete a physical examination including measurement of active and passive shoulder flexion. Range of motion measurements will be utilized for direct comparison and to determine the onset of pain during passive motion. Shoulder flexion will be measured utilizing goniometric procedures described elsewhere.[24,25] Active range of motion testing will be performed in standing and passive range of motion testing will be performed in supine.

After the first rater has completed their examination and prior to any intervention that may change the shoulder symptom irritability, a second rater, blinded from the first rater's assessment, will then examine and rate the subject (Appendix C). In addition to the shoulder symptom irritability rating, both raters will also be asked to provide a treatment intensity recommendation based upon the examination findings (Appendix C). Data collection forms will be placed in a sealed envelope and sent via interoffice mail for analysis. To maintain rater blinding, raters will be asked to not discuss ratings until data collection is complete.

Data Collection and Storage

Data will be collected for a period of 6 months. All data will be kept on a secure, password-protected server (RedCap, Nashville, TN; https://redcap.slhn.org/).

Section D: Statistical Analysis

Descriptive statistics will be used to characterize both raters and patients. Frequencies will be utilized for categorical variables, and means with standard deviations for continuous variables.

A repeated measures design, utilizing two raters per subject, will be utilized to determine inter-rater reliability. The raters will independently rate the subject's shoulder symptom irritability level utilizing the recently developed shoulder symptom irritability scale.[4,6] The inter-rater reliability will be evaluated using the PABAK-OS statistic.[1,3] For evaluation of statistical significance, a two-tailed confidence interval will be utilized with α set to 0.05, and the null hypothesis will be that the PABAK-OS will be <0.40.[3]

Analysis of variance with post-hoc analysis will be utilized for evaluation of differences in patient reported functional limitation and pain subscales between shoulder symptom irritability groups. For evaluation of statistical significance, α will be set to 0.05.

Lastly, to evaluate correlation between intervention intensity and diagnosed level of shoulder symptom irritability, the PABAK-OS statistic will be used. Additionally, independent t-tests will be utilized to evaluate for difference between groups for hypotheses 1 and 2 of aim 3. For evaluation of statistical significance, α will be set to 0.05.

Section E: Limitations and Potential Problems

One potential problem is the need to have more than one clinician trained and available to rate the subjects at all times. Many clinics in this regional hospital network have fewer than three physical therapists and thus, there will be a risk of potential subject loss during the reliability phase. I intend to address this barrier via incentives derived from grant application and via administrative support as the hospital network has a defined educational and research vision.

A limitation to this study is the use of physical therapists and consecutive patients from a single regional hospital network. However, the regional hospital network encompasses over 30 locations with over 80 physical therapists, 18 of which are clinical specialists. Furthermore, the need to have more than one clinician trained and available to rate the subjects at all times could potentially lead to subject loss during the reliability phase.

Another limitation of this study would be the limitation of data in aim 3 to only those subjects who had complete agreement between raters. This would potentially reduce the power of this part of the study. However, the risk to internal validity by utilizing the subjects without complete agreement would be a greater threat to the study than the limitation of power to aim 3 and, to minimize the effect of this limitation, sample size will be twice the size needed to power the study at 80%.

Additionally, the FOTO functional status instrument is a proprietary measure, and while it is utilized nationally and internationally, it is not likely that it will be universally used due to its proprietary nature, thus limiting the generalizability of that aspect of the study. Finally, the data obtained regarding clinician outcome trends is retrospective rather than prospective. While longitudinal data would be ideal, the aim of utilizing retrospective data is to determine if further investigation utilizing longitudinal data is necessary, given the time and financial implications of such a study.

APPENDIX A: IRB INFORMED CONSENT - SUBJECTS

St. Luke's University Health Network
Informed Consent Document for Human Subjects Research

Department: Physical Therapy at St. Luke's

Principal Investigator: Stephen Kareha, DPT **Telephone**: 484-426-2544

Co-investigator: Alicia Fernandez-Fernandez, DPT, PhD **Telephone**: 954-262-1653

Co-investigator: Philip McClure, PT, PhD **Telephone**: 215-572-2863

Medical Study Title: Shoulder Symptom Irritability: A Single-Blinded Observational Study

Lay Study Title: Shoulder Symptom Irritability Testing

Sponsor: None

What Is Informed Consent?

You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a committee that reviews, approves and monitors research involving humans. Before you can make a decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form, once you understand the study and have decided to participate. If you don't understand something about the study or if you have questions, you should ask for an explanation before signing this form;
- Being given a copy of the signed and dated consent form to keep for your own records.

What is the purpose of this study?

Shoulder pain is a large medical and economic problem. Each person that is treated for shoulder pain has a unique case, however, research is continually being performed to try to help medical providers better treat these patients. One way we are trying to enhance this is by developing a tool for classifying the level of "shoulder symptom irritability," or pain and dysfunction levels, of patients with shoulder pain. This study is looking at the reliability (or accuracy) and use of this irritability scale between many different physical therapists.

How many individuals will participate in the study and how long will the study last?

90 patients will participate at St. Luke's University Health Network. Your involvement in the study will last about 1 day.

What will I have to do during the study?

Whether or not you choose to participate, your treatment and care will not change or be affected. Your physical therapist will still examine, evaluate, and treat you as they would regardless of participation in the study. Your involvement includes: answering your therapists questions in regards to pain levels, filling out a functional activity questionnaire, and discussing your condition with your physical therapist.

What are the risks or discomforts involved?

There are no side effects or risks for participating in the study and, as stated before, your treatment will not differ whether you choose to participate in the study or not.

Are there alternatives to being in the study?

You do not have to participate in this study.

HIPAA Authorization: How will privacy and confidentiality (identity) be protected?

Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies you personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that you may see and review your St. Luke's University Health Network medical records at any time. However, in a research study, you may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

If you join this study, the following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of St. Luke's University Health Network involved in this specific study, including the Institutional Review Board (IRB), and your health insurance company (if necessary for billing for standard medical care). It may also be provided to other people or groups as follows:

- Researchers at Arcadia University
- Researchers at Nova Southeastern University

Your PHI may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- With any person or agency required by law.

The following information will be provided to the study sponsor and other entities noted above:

Study data for analysis: Questionnaire results and physical examination results
Demographic data: None

If you develop an illness or injury during the course of your participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study. Your PHI may be used/disclosed until the end of the research study.

You may quit the study and revoke permission to use and share your PHI at any time by contacting the principal investigator, in writing, at: Dr. Stephen Kareha, 501 Cetronia Rd., Suite 145, Allentown, PA 18104. If you quit the study further collection of PHI will be stopped, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your medical records. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

After your information is shared with others, like the sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose information about you only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. When using the information in these ways, the sponsor may share it with other researchers, its business partners, or companies hired to provide research-related services. However, your name will never appear in any sponsor forms, reports, databases, or publications, or in any future disclosures by the sponsor.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, this Web site will include a summary of the results. You can search this Web site at any time.

Will I benefit from being in this study?

You may not benefit from being in this research, but we hope that what we learn may be helpful to future patients or society in general.

Will I be paid for being in this study?

You will not receive payment for your participation in this study.

In addition, you will not be paid if inventions and/or patents are developed from the study results.

Will I be told about any new findings?

Anything learned during the study, beneficial or not, that may affect your health or your willingness to continue in the study, will be told to you and explained.

Are there costs related to being in this study?

There are no costs associated with being in this study beyond normal physical therapy care.

Can I be removed from the study or quit the study?

Your decision to participate in this research study is entirely voluntary. You have been told what being in this study will involve, including the possible risks and benefits.

Your participation in this research project may be terminated by the study doctor without your consent for any reason that he/she feels is appropriate or if your pain is not primarily coming from your shoulder.

You may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting your ability to receive medical care at St. Luke's University Health Network.

If you withdraw from this study, you may continue treatment with your St. Luke's University Health Network doctor, or you may seek treatment from another doctor of your choice.

Should you decide to withdraw from the study, please be sure to inform the study doctor. Additional tests or procedures may be needed to ensure your safety. The study doctor will explain why these tests or procedures are necessary.

CONTACT INFORMATION

Telephone number for questions about your rights as a research participant	St. Luke's University Health Network Institutional Review Board	484-526-6742
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. Stephen Kareha listed at the beginning of this form	484-426-2544

By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.

You affirm that you have read this consent form, and have been told that you will receive a copy.

You also authorize the use and disclosure of your health information to the parties listed in the HIPAA authorization section of this consent for the purposes as described.

_____
Your Name *(please print or type)*

_____ _____
Your Signature Date

_____
Name of Person Conducting Consent

_____ _____
Signature of Person Conducting Consent Date

APPENDIX B: IRB INFORMED CONSENT - RATERS

St. Luke's University Health Network
Informed Consent Document for Human Subjects Research

Department: Physical Therapy at St. Luke's

Principal Investigator: Stephen Kareha, DPT **Telephone**: 484-426-2544

Co-investigator: Alicia Fernandez-Fernandez, DPT, PhD **Telephone**: 954-262-1653

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Medical Study Title: Shoulder Symptom Irritability: A Single-Blinded Observational Study

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- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form, once you understand the study and have decided to participate. If you don't understand something about the study or if you have questions, you should ask for an explanation before signing this form;
- Being given a copy of the signed and dated consent form to keep for your own records.

What is the purpose of this study?

Shoulder pain is a large medical and economic problem. Each person that is treated for shoulder pain has a unique case, however, research is continually being performed to try to help medical providers better treat these patients. One way we are trying to enhance this is by developing a tool for classifying the level of "shoulder symptom irritability," or pain and dysfunction levels, of patients with shoulder pain. This study is looking at the reliability (or accuracy) and use of this irritability scale between many different physical therapists.

How many individuals will participate in the study and how long will the study last?

25 raters will participate at St. Luke's University Health Network. Your involvement in the study will last about 6 months.

What will I have to do during the study?

Whether or not you choose to participate, your employment and eligibility for promotion will not change or be affected. Your involvement includes: reading of the Staged Approach for Rehabilitation Classification: Shoulder Disorders with special focus on the section regarding Level 3 classification and Table 3, a short online narrated presentation to reinforce understanding of the content, and completing rating forms for patients with shoulder pain.

What are the risks or discomforts involved?

There are no side effects or risks for participating in the study and, as stated before, your employment and eligibility for promotion will not differ whether you choose to participate in the study or not.

Are there alternatives to being in the study?

You do not have to participate in this study.

HIPAA Authorization: How will privacy and confidentiality (identity) be protected?

Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies you personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that you may see and review your St. Luke's University Health Network medical records at any time. However, in a research study, you may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

If you join this study, the following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of St. Luke's University Health Network involved in this specific study, including the Institutional Review Board (IRB), and your health insurance company (if necessary for billing for standard medical care). It may also be provided to other people or groups as follows:

- Researchers at Arcadia University
- Researchers at Nova Southeastern University

Your PHI may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- With any person or agency required by law.

The following information will be provided to the study sponsor and other entities noted above:

Study data for analysis: Questionnaire results and physical examination results
Demographic data: None

If you develop an illness or injury during the course of your participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study. Your PHI may be used/disclosed until the end of the research study.

You may quit the study and revoke permission to use and share your PHI at any time by contacting the principal investigator, in writing, at: Dr. Stephen Kareha, 501 Cetronia Rd., Suite 145, Allentown, PA 18104. If you quit the study further collection of PHI will be stopped, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your medical records. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

After your information is shared with others, like the sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose information about you only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. When using the information in these ways, the sponsor may share it with other researchers, its business partners, or companies hired to provide research-related services. However, your name will never appear in any sponsor forms, reports, databases, or publications, or in any future disclosures by the sponsor.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, this Web site will include a summary of the results. You can search this Web site at any time.

Will I benefit from being in this study?

You may not benefit from being in this research, but we hope that what we learn may be helpful to future patients or society in general.

Will I be paid for being in this study?

You will receive payment for your participation in this study. You will receive a $5 gift certificate for each patient you rate in this study. Should study payments meet or exceed $600 in one calendar year, you will be issued a 1099 Form to report study payments as taxable income as required by the IRS. ***We do not foresee your participation falling under the reportable income parameters as there are only a total of 90 study subjects being enrolled, thus the maximum you will be paid for your participation is $450.***

In addition, you will not be paid if inventions and/or patents are developed from the study results.

Will I be told about any new findings?

Anything learned during the study, beneficial or not, that may affect your health or your willingness to continue in the study, will be told to you and explained.

Are there costs related to being in this study?

There are no costs associated with being in this study beyond normal physical therapy practice.

Can I be removed from the study or quit the study?

Your decision to participate in this research study is entirely voluntary. You have been told what being in this study will involve, including the possible risks and benefits.

Your participation in this research project may be terminated by the study doctor without your consent for any reason that he/she feels is appropriate or if your pain is not primarily coming from your shoulder.

You may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting your ability to receive medical care at St. Luke's University Health Network.

If you withdraw from this study, you may continue treatment with your St. Luke's University Health Network doctor, or you may seek treatment from another doctor of your choice.

Should you decide to withdraw from the study, please be sure to inform the study doctor. Additional tests or procedures may be needed to ensure your safety. The study doctor will explain why these tests or procedures are necessary.

CONTACT INFORMATION

Telephone number for questions about your rights as a research participant	St. Luke's University Health Network Institutional Review Board	484-526-6742
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. Stephen Kareha listed at the beginning of this form	484-426-2544

By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.

You affirm that you have read this consent form, and have been told that you will receive a copy.

You also authorize the use and disclosure of your health information to the parties listed in the HIPAA authorization section of this consent for the purposes as described.

_____
Your Name *(please print or type)*

_____ _____
Your Signature Date

_____
Name of Person Conducting Consent

_____ _____
Signature of Person Conducting Consent Date

St. Luke's University Health Network
Stephen Kareha
Director, Orthopaedic Physical Therapy Residency
484-426-2544
IRB Control #: 2016-61

APPENDIX C: SURVEYS AND DATA COLLECTION FORMS

Subject #_____

PHYSICAL THERAPY AT StLuke's

Rater Information

Name: _____

Age: _____

Years of Practice: _____

Advanced Certifications Held:

- ☐ OCS
- ☐ SCS
- ☐ FAAOMPT
- ☐ Other _____

Gender: ☐ Male ☐ Female

Entry Level Degree:

- ☐ BS
- ☐ MS
- ☐ DPT

Highest Earned Degree:

- ☐ BS
- ☐ MS
- ☐ DPT
- ☐ PhD, ScD, EdD

St. Luke's University Health Network
Stephen Kareha
Director, Orthopaedic Physical Therapy Residency
484-426-2544
IRB Control #: 2016-61

For Office Use Only:
Subject #_____

Inclusion Criteria

- ☐ 18 years old or older
- ☐ Chief complaint of shoulder pain

Exclusion Criteria

- ☐ Pain or symptoms distal to the elbow
- ☐ History of ipsilateral shoulder surgery
- ☐ Active or passive cervical spine ROM reproduces shoulder pain
- ☐ Positive Spurling's test
- ☐ Not literate in the English language
- ☐ Unable to complete the self-report functional questionnaires

☐ Subject meets BOTH inclusion criteria AND does not meet ANY of the exclusion criteria

☐ Subject does NOT meet inclusion criteria OR meets one of the exclusion criteria

Stephen Kareha
Director, Orthopaedic Physical Therapy Residency
484-426-2544
IRB Control #: 2016-61

PENN/ASES SHOULDER SCORE

Subject #

Dominant Hand:	Gender:	Affected Arm:
L R Both (circle one)	M F (circle one)	L R Both (circle one)

PENN SHOULDER SCORE
Part I: Pain & Satisfaction: Please circle the number closest to your level of pain or satisfaction

	office use only
How bad is your pain today? 0 1 2 3 4 5 6 7 8 9 10 No Pain … Worst Pain Possible	---------- (10 - #circled = __ x 5= __) ASES Pain
Pain at rest with your arm by your side: 0 1 2 3 4 5 6 7 8 9 10 No Pain … Worst Pain Possible	(10 - # circled)
Pain with normal activities (eating, dressing, bathing): 0 1 2 3 4 5 6 7 8 9 10 No Pain … Worst Pain Possible	_____ ('10 - # circled) (score "0" if not applicable)
Pain with strenuous activities (reaching, lifting, pushing, pulling, throwing): 0 1 2 3 4 5 6 7 8 9 10 No Pain … Worst Pain Possible	('10 - # circled) (score "0" if not applicable)
PAIN SCORE:	=___/30
How satisfied are you with the current level of function of your shoulder? 0 1 2 3 4 5 6 7 8 9 10 Not Satisfied … Very Satisfied	=___/10 (# circled)

PLEASE TURN OVER TO COMPLETE QUESTIONNAIRE

OFFICE USE ONLY

Today's Date: / /

	PENN SHOULDER SCORE (PSS)	ASES SHOULDER SCORE (ASES)
Pain	/30	/50
Satisfaction	/10	
Function	/60	/50
TOTAL	/100	/100

PENN SHOULDER SCORE/ASES SHOULDER SCORE Part II: Function: Please circle the number that best describes the level of difficulty you might have performing each activity.	No difficulty	Some difficulty	Much difficulty	Can't do at all	Did not do before injury
1. Reach the small of your back to tuck in your shirt with your hand.	3	2	1	0	X
2. Wash the middle of your back/hook bra. (ASES #3)	3	2	1	0	X
3. Perform necessary toileting activities. (ASES #4)	3	2	1	0	X
4. Wash the back of opposite shoulder.	3	2	1	0	X
5. Comb hair. (ASES # 5)	3	2	1	0	X
6. Place hand behind head with elbow held straight out to the side.	3	2	1	0	X
7. Dress self (including put on coat and pull shirt of overhead. (ASES # 1)	3	2	1	0	X
8. Sleep on affected side. (ASES # 2)	3	2	1	0	X
9. Open a door with affected side.	3	2	1	0	X
10. Carry a bag of groceries with affected arm.	3	2	1	0	X
11. Carry a briefcase/small suitcase with affected arm.	3	2	1	0	X
12. Place a soup can (1-2 lbs.) on a shelf at shoulder level without bending elbow.	3	2	1	0	X
13. Place a one gallon container (8-10 lbs.) on a shelf at shoulder level without bending elbow.	3	2	1	0	X
14. Reach a shelf above your head without bending your elbow. (ASES # 6)	3	2	1	0	X
15. Place a soup can (1-2 lbs.) on a shelf overhead without bending your elbow.	3	2	1	0	X
16. Place a one gallon container (8-10 lbs.) on a shelf Overhead without bending your elbow. (ASES # 7)	3	2	1	0	X
17. Perform usual sport/hobby. (ASES # 9)	3	2	1	0	X
18. Perform household chores (cleaning, laundry, cooking).	3	2	1	0	X
19. Throw overhand/swim/overhead racquet sports. (circle all that apply to you) (ASES # 8)	3	2	1	0	X
20. Work full-time at your regular job. (ASES # 10)	3	2	1	0	X
SCORING: (office use only)	PSS	PSS	PSS	PSS	PSS
PSS Total of all columns = _____ (a)	_____	_____	_____	_____	_____
Number of "X"s" x 3 =_____ (b), 60 – _____ (b) = _____ (c)					
(If no "X"s" are circled, function score = total of columns)	ASES	ASES	ASES	ASES	
PSS Function Score = ____(a) ÷ ____(c) = ____ x 60 = ____ of 60	_____	_____	_____	_____	
ASES Score = _____					
Total of shaded columns: ____ x 5/3 = _____ of 60					

Physical Therapy at St. Lukes - Physical Therapy at St. Luke's - West End

INTAKE FUNCTIONAL STATUS SUMMARY

Patient:
ID#
Date of Birth:
Initial DOS:
Body Part:
Impairment:
Surgery Type:
Surgery Date:

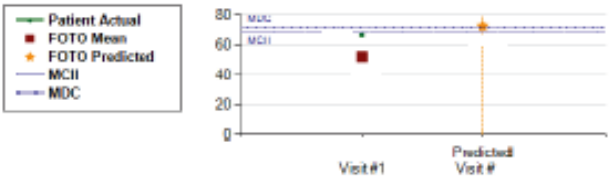
Risk-Adjustment Criteria

Care Type:
Body Part:
Severity:
Age:
Acuity:
Gender:
Comorbidities:
Payer:
Fear Avoidance:
Surgery Status:

Functional Status Measures:	Intake Score	Interpretation of FS Scores/Stages Value
Patient's Physical FS Primary Measure		Patient's intake functional measure is out of (higher number = greater function).This FS measure places the patient in **Stage 4** and means the patient has good shoulder function.
Risk Adjusted Statistical FOTO*		Given the patient's risk-adjustment variables, like-patients nationally had a FS score of 52, **Stage 3**, at intake.

MCII = Points of change that is important to the patient)

MDC = Represents the smallest threshold to identify points of change that is greater than measurement error)



Rehabilitation Resource Predictor*	Predicted Value	Interpretation of Predicted Value
Points of Physical FS Change		
Discharge FS Score		Given this patient's risk-adjustment variables, and the actual intake FS score, FOTO predicts this patient will experience at least an increase in function of 6 points (to 73 or higher), putting them in the **Stage 4** level or higher at discharge.
Visits per Episode		
Duration of Episodes in Days		
Satisfaction Score		

Stage: 1 Exceedingly limited shoulder
Stage: 2 Poor shoulder
Stage: 3 Fair shoulder
Stage: 4 Good shoulder
Stage: 5 Excellent shoulder

* The above predictions are calculated for
1) patients who have previously utilized rehabilitation services from FOTO's national aggregate database and
2) using sophisticated analyses to risk adjust for the impact of ten important variables known to influence outcomes including Care type, Body Part/Impairment, Severity, Age, Acuity, Gender, Surgery, Fear Avoidance, Payer, and Comorbidities.

What Does This Mean For Improving Function

This chart displays the patient responses to the functional activities contained in the intake survey that generated the intake FS score. The activities are presented in the descending order of difficulty. Responses listed in the Intake column are the survey item levels of ability at intake. Given the change experienced by the comparative risk adjusted group in FOTO's data, it is anticipated the patient should be able to do the activities at the level indicated in the predicted column or higher at the completion of care, to place the patient in the predicted **Stage 4** functional level by discharge.

Patient responses to functional health questions that indicate dysfunction were as follows:

Activity (Question)	Amount of Limitation (Response) at Intake	Amount of Limitation (Response) predicted	Functional Limitation
How much difficulty do you have using your affected arm to place a 50 lb. box on a shelf overhead?			Other PT/OT Primary - G8990
How much difficulty do you have using your affected arm to place a 25 lb. box on a shelf overhead?			Other PT/OT Primary - G8990
Work overhead for more than 2 minutes?			Other PT/OT Primary - G8990

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INTAKE FUNCTIONAL STATUS SUMMARY

Patient: **Primary Body Part:** Shoulder **Initial DOS:**

Patient responses to functional health questions that indicate dysfunction were as follows:

Touch an object on the back seat while sitting in the front seat of a car?			Carrying, Moving & Handling Objects - G8984 Other PT/OT Primary - G8990
Reach an overhead shelf?			Other PT/OT Primary - G8990
Reach a shelf that is at shoulder height?			Carrying, Moving & Handling Objects - G8984

If the patient reaches the anticipated level on the above activities, other **Stage 4** activities the patient should be able to perform include:

- Adjusting the back of your collar with your affected hand - No difficulty
- Combing or brushing your hair using your affected arm - No difficulty
- Pull a medium weight object (5-10 lbs) from under a bed - No difficulty
- Move a heavy skillet (eg, cast iron skillet) from one stove burner to another - No difficulty
- Steady a jar while you loosen the jar lid - No difficulty
- Taking off glasses or sunglasses using your affected arm - No difficulty
- Place a can of soup (1 lb) on a shelf at shoulder height - No difficulty
- Reaching across to the middle of the table with your affected arm to get a salt shaker while sitting - No difficulty
- Turn a steering wheel in the opposite direction as your affected arm (eg, turn left if it is your right shoulder that is affected) - No difficulty
- Reach and pull the string that controls a light or fan - No difficulty

Additional Intake Information Gathered for the Clinician

- **Physician Referral:** Insurance Referral:
- **Patient reports other health problems as:**
- **BMI:**
- **Exercise prior to onset:**
- **Prescription medicine:**
- **Surgery:**
- **Fear avoidance belief about physical activity:**

Additional Surveys

	Intake	Scale
Physical Fear		

Physical Fear

Physical Fear Results:

	Fear Avd Belief About Phys Activ
Intake	

Crosswalk

	Intake	Scale
DASH		

Mathematical crosswalk from the Shoulder FS score to the DASH. For the DASH, a higher score indicates greater disability.

Physical Therapy at St. Lukes - Physical Therapy at St. Luke's - West End

INTAKE FUNCTIONAL STATUS SUMMARY

Patient: **Primary Body Part:** Shoulder **Initial DOS:**

Pain Assessment Summary

Intensity

In the last 24 hours the level of pain was rated at: /10
In the last 30 days, the level of least pain was rated at: /10
and the level of most pain was rated at: /10

Character

Qualities of Pain
Patient reports that the pain feels

The intensity is

Influence of Activity
The pain is increased by

The pain is reduced by

CMS G-Codes

FOTO Shoulder Survey
CMS G-Code Options**

Functional Limitations Assessed in FOTO Shoulder Survey

Current Status	Goal Status	D/C** Status	Asked	Descriptor
G8984	G8985	G8986	2	Carrying, moving & handling objects functional limitation
G8987	G8988	G8989	0	Self care functional limitation
G8990	G8991	G8992	5	Other physical or occupational primary functional limitation

**Only report if this is a one time visit

CMS Impairment/Limitation/Restriction for FOTO Shoulder Survey

	Status	Limitation	G-Code	CMS Severity Modifier
Intake				
Predicted				

*Based on FOTO predicted change score

× _____
Clinician:

* Mean, Risk Adjusted, Intake Composite FS measures from FOTO aggregate database
** As indicated by the ICF assignments to the survey items in the FOTO survey used

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St. Luke's University Health Network
Stephen Kareha
Director, Orthopaedic Physical Therapy Residency
484-426-2544
IRB Control #: 2016-61

For Office Use Only:
Subject #_____

Pain At Night or At Rest

- ☐ Constantly
- ☐ Intermittently
- ☐ None

AROM compared to PROM

- ☐ AROM less than (<) PROM
- ☐ AROM nearly equal to (≈) PROM
- ☐ AROM equal to (=) PROM

Pain reproduction with ROM

- ☐ Prior to end range
- ☐ At end range
- ☐ None or with overpressure at end range

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Stephen Kareha
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Subject #_____

PHYSICAL THERAPY AT StLuke's

Irritability Rating

Based upon your examination of this patient, please rate the level of shoulder symptom irritability:

☐ High ☐ Moderate ☐ Low

☐ Unclassifiable (Reason:_____)

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Director, Orthopaedic Physical Therapy Residency
484-426-2544
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For Office Use Only:
Subject #_____

Which of the below treatments strategies would BEST be used for this patient TODAY?

(Select only one)

☐ Provide moderate–high physical stress
Address specific impairments
Restore of high-demand functional activity

☐ Provide mild–moderate physical stress
Address specific impairments
Restore basic-level functional activity

☐ Minimize Physical Stress
Modify activities
Monitor impairments

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Stephen Kareha
Director, Orthopaedic Physical Therapy Residency
484-426-2544
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PHYSICAL THERAPY AT StLuke's

For Office Use Only:
Subject #_____

Do you plan to provide any of the below treatments to this patient TODAY?

1. **Exercises addressing muscular weakness** ☐ Yes ☐ No
   If yes, select one option below:
   - ☐ Active range of motion (no external load)
   - ☐ Mild-moderate resistive strength training
   - ☐ Moderate-high resistive strength training

2. **Exercises addressing mobility** ☐ Yes ☐ No
   If yes, select one option below:
   - ☐ Range of motion exercises (non-end range stress; pain free)
   - ☐ Range of motion exercises (end range stress; transient or shorter hold times)
   - ☐ Range of motion exercises (end range stress; longer duration hold times)

3. **Shoulder joint mobilizations** ☐ Yes ☐ No
   If yes, select one option below:
   - ☐ Low grade; not achieving end range
   - ☐ High grade; achieving end range

4. **Electrical Agents for pain control (e.g. TENS)** ☐ Yes ☐ No

5. **Thermal modalities** ☐ Yes ☐ No
   If yes, select one option below:
   - ☐ For pain control or relaxation
   - ☐ To facilitate tissue extensibility

6. **Recommendations for Functional Activity** ☐ Yes ☐ No
   If yes, select one option below:
   - ☐ Avoid provocative functional activities
   - ☐ Encourage basic-level functional activities
   - ☐ Encourage high-demand functional activities