

## ASES Multicenter Shoulder PJI Database

### Background Information and Frequently Asked Questions (FAQ)

#### Background:

Shoulder periprosthetic joint infections (PJIs) can be difficult to diagnose and manage. Unlike PJI of the hip and knee, the bacteria involved with shoulder PJI (eg, *Cutibacterium*) are generally of lower virulence. The bacteria are often present on the skin at the time of index arthroplasty and are thought to inoculate the deeper tissues when incision is made. Due to their low virulence, infections with these bacteria can often occur without the usual signs and symptoms of infection such as erythema, drainage, or sinus tract formation. Therefore, common diagnostic criteria for PJI of the hip and knee may not be applicable for the shoulder. Furthermore, microbiologic results may play a pivotal role in management and are not often available until days after the surgery is complete.

At the 2018 International Consensus Meeting in Philadelphia, the first consensus definition for shoulder PJI was established (see <https://icmphilly.com/icm-2018-shoulder-document/>). Three criteria allow for definition of a “definite” PJI: sinus tract, gross pus, and two positive cultures with the same virulent organism. Outside of “definite” PJI, there are numerous minor criteria that assist in the clinician in defining “probable”, “possible”, or “unlikely” PJI including wound drainage, culture results, humeral loosening, frozen section results, synovial aspiration results, ESR/CRP values, and presence of cloudy fluid (see <https://icmphilly.com/questions/what-are-the-diagnostic-criteria-of-shoulder-periprosthetic-joint-infection-pji/>). These minor criteria were based on existing literature and consensus of the delegates present at this meeting but have not been validated.

Our goals with this database are to study 1) patient, shoulder, and procedural characteristics predictive of recurrent PJI, and 2) the association of the 2018 ICM minor criteria on recurrent PJI and patient-reported outcomes. Data from this study will help refine our consensus definition for shoulder PJI and optimize prevention and management of shoulder PJI.

#### Suggested inclusion criteria:

- English-speaking adults
- 18 years of age or older
- Undergoing revision shoulder arthroplasty

#### Suggested exclusion criteria:

- Recent (<3 months) or ongoing treatment for presumed shoulder PJI

#### Data collected:

Preoperative data will include patient demographics (age, sex, BMI, ASA class, tobacco use, narcotic use, diabetes, insurance status, race, marital status), shoulder characteristics (laterality, sinus tract, wound drainage, radiographic loosening, previous surgeries), perioperative data (pre-operative antibiotic use, preoperative laboratory values, pre-operative aspiration or biopsy, indication for revision, frozen section, presence of pus, cloudy fluid, membrane, osteolysis, surgery performed, infection adjuvant treatments), postoperative microbiology results, post-operative antibiotic management, preoperative and 1, 2, 5, and 10 year postoperative patient-reported outcomes (ASES, SST, SANE, and VR-12/SF-12), and postoperative complications or revision surgeries. Both an abridged codebook and a detailed codebook are provided with a full list of variables.

#### Statistical analysis:

Continuous variables will be presented as means with standard deviations, and categorical variables will be presented as frequencies or percentages. Multivariate analysis will be performed to determine independent predictors (patient, shoulder, and procedure characteristics) for recurrent shoulder PJI (using the ICM definition for “definite” PJI as well as revision surgery with positive cultures) and patient-reported outcomes (ASES, SST, SANE, VR-12/SF-12).

## **FAQ: Database Workflow**

### **What are the institutional requirements for participation?**

Each institution that participates in the database must perform >10 revision shoulder arthroplasties annually. To maintain active status as a participant, each institution will need to:

1. Submit 5 or more revision arthroplasties annually
2. Maintain >80% completion of physician surveys within 3 weeks
3. Maintain >70% completion of patient surveys within 3 months

### **What patients should I enroll into the database?**

Participating surgeons should enroll ALL consecutive patients undergoing revision shoulder arthroplasty (even if PJI is not suspected) that have not had recent surgical treatment for presumed shoulder PJI.

### **Should I enroll only patients that I suspect are infected?**

No. You should enroll all revision shoulder arthroplasty patients regardless of suspicion for infection. Multiple studies have demonstrated our inability to properly diagnose infection pre-operatively and intra-operatively, so enrolling consecutive patients is important. This is essentially a revision shoulder arthroplasty database that should provide useful information regarding the diagnosis and management of PJI but also may be used to study revision shoulder arthroplasty.

### **When should I enroll a patient?**

Enrollment of a patient should occur 1) after you consent the patient for the study, and 2) when you provide the patient with a surgical date. Because survey distribution is anchored on the surgical date, you should not enroll a patient until the surgical date is known.

You will visit the ITHS website at <https://redcap.iths.org/> and add a new record for the patient. It will ask you to confirm that the patient was consented and to enter the study contact information. This will trigger the initial physician survey to be sent.

### **What surveys are we collecting?**

Patients will fill out the same questionnaires pre-operatively and at 1, 2, 5, and 10 years. The patient surveys include:

- ASES
- SST
- VR-12 or SF-12
- SANE

Physicians will fill out multiple surveys at the following timepoints which are outlined in the flowchart in Figure 1 at the end of this document. The physician surveys include:

- Pre-operative (patient demographics, baseline shoulder characteristics)
- Peri-operative (preoperative labwork/treatment, intraoperative findings)
- Microbiology/antibiotic information (results of pre-operative and revision cultures, post-op antibiotic therapy)
- Annual follow-up (recurrent PJI, subsequent revision surgery, radiographic failure)

### **What questions are asked at each of the surveys?**

A list of all questions and variables are attached in the abridged and detailed REDCap codebook documents. Questions or variables are subject to be modified by the coordinating site after study implementation, if needed. Significant amendments to the questions or variables will be reported to the group.

## **How do I choose whether to have patient-reported outcomes (PROs) sent to me or to the patient?**

The first physician survey will ask whether the surgical team or the patient should receive patient reported outcome surveys by email.

If you already use another method of obtaining these PROs from patients (OBERD, SOS, or by your normal clinical workflow), it is suggested that you have the PROs sent to the surgical team contact to fill out. This will allow you to be notified when these PROs are due. The PROs can be imported into REDCap by a .csv file.

If you choose to have the PRO sent directly to the patient, the surveys will be automatically sent out at the correct timepoints as long as you provide a valid e-mail address.

## **If I choose to have REDCap send surveys directly to the patient's e-mail address, when do they receive the preoperative questionnaires?**

If you are going to have REDCap send automated surveys to the patient's e-mail address, it is highly suggested that you fill out the first physician survey IMMEDIATELY – the patient will not receive the preoperative questionnaires until this is completed.

We do suggest that you try and gather the questionnaires in person when seeing the patient at the pre-operative appointment, then entering this information into REDCap after the visit. *If the patient does not fill out the survey prior to surgery, the pre-operative questionnaires will be invalid.*

## **Should I use the SF-12 or the VR-12?**

If patients are set up to receive surveys directly by e-mail, the VR-12 will be sent, and the aggregate scores will be calculated for you.

If the surgical team administers the survey to patients, you have the option of using the SF-12. However, *you will be required to calculate the aggregate scores on your own and enter these into REDCap.*

## **How can we withdraw a patient from the study?**

Login to redcap.iths.org, select this study's REDCap project, then select 'Add / Edit Records'. Once in the patient's record, select the instrument 'Subject Withdrawal' at the time point closest to the patient's withdrawal and answer the questions in the instrument. This will prevent further surveys from being scheduled. The 'Survey Distribution Tools' function can be used to double check that no surveys are already scheduled.

## **FAQ: Clinical Management of Patients**

### **Should I change my pre-operative workup and management of patients for this database?**

No. We are not asking you to change any of your usual pre-operative interventions for shoulder PJI. If you typically do not perform a joint aspiration in clinic or an arthroscopic or open biopsy prior to formal open revision, you should not change your practice.

It is suggested, however, that you do try to obtain the following:

- Serum ESR/CRP
- Frozen section at the time of surgery
- Synovial aspiration at time of open revision after skin incision but prior to subscap takedown
  - Synovial lab priority: culture, synovial WBC/neutrophil %, alpha-defensin
- 5 or more deep tissue cultures at time of revision if you choose to get cultures

### **If I do subsequent surgery after the first revision, how do I log these?**

At 1 year, 2 years, 5 years, and 10 years, you will receive a survey that includes questions about whether any revision surgeries were performed. These will not be as detailed as the peri-operative survey from the initial revision, but they will ask about what was done and what the results of any cultures were. Regardless of whether the patient needed further surgery, the anchor point for all surveys will always remain as the initial revision.

### **Does the anchor date change with a two-stage revision?**

Unfortunately, changing the anchor date to the second stage becomes problematic for the reporting system, and so the anchor date is not changed even if a two-stage revision is planned.

## **FAQ: IRB and DUA**

### **Will I need IRB approval, or can I use a data use agreement (DUA)?**

*You will need both* an IRB approval and DUA to participate. We will provide a templated DUA and encourage use of this form unless your institution requires something else.

### **Is there a template IRB protocol for this study?**

Not all sites will be consenting participants specifically to this multicenter study and instead may be adapting already implemented IRB protocols to include this study. We have developed the multicenter IRB approval to be open to both existing IRB protocols for revision shoulder arthroplasty studies as well as new IRB protocols. However, the first page of this document can be used as a guideline for IRB submission.

If you are creating a new IRB approval for this study, we will provide the UW IRB approval letter, but a formal protocol template is not a part of the UW IRB protocol. Please reference the invitation letter for IRB details. We will assist you with specific questions regarding the design of your IRB protocol. Your IRB application should take into account the variables listed at the end of this document and list the patient-reported outcomes including the ASES, SST, SANE, and VR-12.

### **Suggested inclusion criteria:**

- English-speaking adults
- 18 years of age or older
- Undergoing revision shoulder arthroplasty (given that signs and symptoms of infection are not always readily apparent, to study the definition and management of shoulder PJI well, we need to enroll all patients undergoing revision arthroplasty, regardless of whether PJI is strongly suspected or not)

### **Suggested exclusion criteria:**

- No recent (<3 months) or ongoing treatment for presumed shoulder PJI

### **Where is the data stored?**

All data will be maintained in REDCap run through the Institute of Translational Health Sciences (ITHS) and University of Washington. Participants can login to the database at this following website: <https://redcap.iths.org/>

### **How will our data be protected in REDCap? Can other institutions see our data?**

All physicians and research staff (besides the coordinating site at University of Washington) will be assigned to a Data Access Group in the REDCap project. Data access groups restrict the users' ability to view data within this project, when a user is assigned to a data access group they can only see the data for their own site. Though the team at the University of Washington site will not be assigned to a data access group, they will not be granted access to any REDCap instruments containing PHI, to the Survey Distribution Tools, or access to exporting any identifiers from any site. PHI will not be visible to anyone outside of your institution.

If you have any additional questions that are not included in this document, you can e-mail Anastasia Whitson ([whitsa@uw.edu](mailto:whitsa@uw.edu)) for IRB/DUA-related questions or Jason Hsu ([jehsu@uw.edu](mailto:jehsu@uw.edu)) for database/workflow-related questions.

**Figure 1. Database flowchart.**

