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# QUESTION 5: What are the diagnostic criteria of shoulder periprosthetic joint infection (PJI)?

**RECOMMENDATION:** See International Consensus Meeting (ICM) definition of shoulder PJI below.

**LEVEL OF EVIDENCE:** Consensus

**DELEGATE VOTE:** Agree: 88%, Disagree: 12%, Abstain: 0% (Super Majority, Strong Consensus)

## INTERNATIONAL CONSENSUS MEETING (ICM) FOR PERIPROSTHETIC JOINT INFECTION: DEFINITION, CATEGORIZATION AND SCORING SYSTEM FOR SHOULDER PJI

### Definite PJI

Meeting one of the following criteria is diagnostic of **definite** periprosthetic shoulder infection:

- A sinus tract communicating with the prosthesis is present
- Gross intra-articular pus
- Two positive cultures with phenotypically-identical virulent organisms

### Evaluation Scoring

Weighted values for all positive tests performed as part of the diagnostic evaluation of a failed shoulder arthroplasty are summed (Table 1).

- Six or greater with identified organism = **probable PJI**
- Six or greater *without* identified organism = **possible PJI**
- Six or less
  - single positive culture virulent organism = **possible PJI**
  - two positive cultures low-virulence organism = **possible PJI**
  - negative cultures or only single positive culture for low virulent organism = **PJI unlikely**

### RATIONALE

The need for a consensus definition of shoulder PJI cannot be understated. A clear definition serves two purposes: (1) to aid in clinical decision making and (2) to provide a framework for consistent future research reporting. Furthermore, acceptance of a definition is a necessary first step in providing a well-tested diagnostic algorithm. As Hsu et al. demonstrated [1], the shoulder research community has used disparate definitions of PJI—likely leading to variable and inconsistent conclusions about the diagnosis and management. Adoption of a uniform definition of PJI for the lower extremity quickly led to hundreds of publications evaluating prevention, diagnosis and treatment of PJI based upon the same consistent diagnostic criteria [2,3]. This task is even more urgent in regard to shoulder arthroplasty due to the unique microbiologic and the ambiguity presented by high rates of positive intraoperative cultures in revision cases that otherwise appear aseptic [4–9]. In order to discuss diagnosis and evaluation of shoulder PJI, it is imperative that the shoulder community begin with a standardized and accepted definition of shoulder PJI.

**TABLE 1. Weighted values for all positive tests performed as part of the diagnostic evaluation of a failed shoulder arthroplasty**

| Minor Criteria | Weight |
|---|---|
| Unexpected wound drainage | 4 |
| Single positive tissue culture (virulent organism) | 3 |
| Single positive tissue culture (low-virulence organism) | 1 |
| Second positive tissue culture (identical low-virulence organism) | 3 |
| Humeral loosening | 3 |
| Positive frozen section (5 PMN in at least 5 high-power fields) | 3 |
| Positive preoperative aspirate culture (low or high-virulence) | 3 |
| Elevated synovial neutrophil percentage (> 80%)* | 2 |
| Elevated Synovial WBC (> 3,000 cells / µL)* | 2 |
| Elevated ESR (> 30 mm/hr)* | 2 |
| Elevated CRP (> 10 mg/L)* | 2 |
| Elevated synovial alpha-defensin | 2 |
| Cloudy fluid | 2 |

PMN, polymorphonuclear leukocyte; WBC, white blood cell; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein
*Beyond six weeks from recent surgery

## Committee Goals

1. Define criteria that establish a diagnosis of shoulder PJI.
2. Provide a common language for research reporting and clinical decision making.
3. The definition should be flexible enough to include the "obvious" suppurative, shoulder PJI, as well as the subtler "stealth" infections and cases where the clinical scenario is unclear.
4. Incorporate the best available evidence in this field.
5. That the definition of shoulder PJI should generally be similar to the Musculoskeletal Infection Society (MSIS) hip and knee definition, but differ according to specific characteristics unique to the shoulder.
    a. Less weight put on positive cultures with low-virulence organisms given the data on this phenomenon in the shoulder.
    b. A larger "grey area" of "possible PJI" to recognize that there are a large number of cases where, given the current state of the field, it is not possible to define as clearly infected or uninfected.
    c. Include a scoring system in order to potentially create objective criteria for sorting these "possible PJI" cases.

## Committee Process

The process undertaken to formulate this definition was a consensus effort relying upon the clinical expertise of numerous shoulder and elbow surgeons who routinely treat shoulder periprosthetic joint infection. First, a systematic review as undertaken to evaluate the definitions in use for shoulder PJI and the evidence for each (this is included in Appendix A). Second, over a year-long process, the 69 ICM delegates (experts in shoulder PJI and infectious disease from 11 countries) performed 75 separate, parallel systematic reviews evaluating aspects of prevention, diagnosis and management of shoulder PJI. Following a Delphi process these reviews were disseminated, discussed and then refined in-person at the Second ICM in Philadelphia (July 2018) where delegates voted on each statement. Each of these 75 reports was used by the definition committee in addition to their own experience to discuss potential definition options. These were refined, voted upon and ultimately accepted at the ICM meeting in Philadelphia. The original MSIS criteria have gone through multiple iterations as the consensus definition has been refined through testing and further research. The definition of shoulder PJI is no different, and we fully expect that as researchers begin to adopt this definition the criteria and weightings may change, as our knowledge and understanding of the evaluation and management of shoulder PJI evolves.

## Rationale for the Definition

While there remains controversy and uncertainty about the definition and management of shoulder PJI, there are cases that are considered to be unquestionably infected. Therefore, a subgroup of "Definite PJI" shoulder PJI was defined to identify these cases. This included the presence of a sinus tract (as discussed Section 2:3, Question 1), gross intra-articular pus, or two separate positive cultures with identical virulent pathogens (as discussed in Section 2:1, Question 1). While specific evidence for these criteria is lacking, a strong consensus existed that if any of these criteria were met, an infection was undoubtedly present. When assessing intra-articular purulence, consideration must be given to other less common inflammatory conditions, including rheumatologic disease and

reactions to metal or other foreign bodies, which rarely incite a process that produces debris or aseptic purulence in shoulder arthroplasty.

As discussed in Section 2:1, Question 1 and Section 2:5, Question 8, the significance of a positive culture may depend upon the number of cultures sent and the degree of growth. Therefore, as discussed in "Diagnosis: Sampling" Question 8, it is recommended that "five deep tissue specimens for culture be obtained from various surgical sites (e.g., capsule, humeral canal, and periprosthetic membranes in the proximal humerus and glenoid)." This should provide sufficient sensitivity for bacterial growth while minimizing the risk of false positives, as discussed in Section 2:1, Question 1. Furthermore, when reporting results we recommend that the number of positive cultures should be reported as a fraction of the total cultures sent (x/y where x = number of positive cultures and y = total number of cultures sampled) and/or the "Shoulder propi score" Section 2:1, Question 2). Lastly, as discussed in Section 2:2, Question 1, cultures should be held for fourteen days to optimize detection of pathogens.

The lack of these defining signs certainly does not exclude the diagnosis of PJI. Therefore, in these less distinct scenarios three categories were established: "Probable PJI," "Possible PJI" and "PJI unlikely." Given the lack of strong evidence defining the clinical significance of low-virulence positive cultures, this stratification allows for clinical guidance and classification of cases for research purposes without grouping heterogenous cases. For classification of these cases, minor criteria were proposed and edited by the group at large. Many of these minor criteria have been discussed in other questions (Table 1). As the significance of a positive result for these minor criteria varies, each criterion was weighted. It was agreed that a threshold score of six would serve as a marker of the increased likelihood of a shoulder PJI, though the committee fully expects that as this definition is tested and refined, the weightings and the thresholds will be improved.

To apply weight for each of these minor criteria, a score was applied to each criterion independently by every member of the shoulder group in attendance. These scores were then averaged and discussed further, resulting in the weighting reported here. To further test the definition, clinical scenarios were proposed and evaluated with the definition (Table 2). In each case, the ICM diagnostic criteria gave a result which the delegates felt, with consensus, described their own clinical conclusions.

Inflammatory markers (synovial fluid white blood cell count and differential, serum erythrocyte sedimentation rate, and serum C-reactive protein) are often elevated during the early postoperative period, and, thus, use in the diagnostic evaluation was limited to beyond six weeks from a recent surgery. There have been multiple studies in the lower extremity demonstrating the impact of surgery on these inflammatory markers [10,11]. Normal thresholds for inflammatory markers in the acute postoperative period after shoulder arthroplasty have not been established.

The formation of this definition provides an important step in improving the care for patients with and understanding of shoulder PJI. Adoption of this definition by those performing research of shoulder PJI will allow for uniform evaluation of study outcomes as researchers, reviewers and readers will all be using the same language. Lastly, we want to emphasize this definition is a first iteration. As the understanding of shoulder PJI evolves and each diagnostic test is further evaluated, it will be necessary to revisit this definition as a community.

## APPENDIX A

### Search Strategy and Study Selection

Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, we conducted a systematic review to identify all studies concerning diagnosis and treat-

**TABLE 2. ICM questions discussing each minor criterion in greater detail**

| Minor Criteria | Question |
|---|---|
| Unexpected wound drainage | Section 2:3, Question 1 |
| Single positive tissue culture (virulent organism) | Section 2:1, Question 1 |
| Single positive tissue culture (low-virulence organism) | Section 2:1, Question 1 |
| Second positive tissue culture (identical low-virulence organism) | Section 2:1, Question 1 |
| Humeral loosening | Section 2:3, Question 2 |
| Positive frozen section (5 PMN in at least 5 high-power fields) | Section 2:3, Question 4 |
| Positive preoperative aspirate culture (low or high-virulence) | Section 2:5, Question 8<br>Section 2:4, Question 9 |
| Elevated synovial neutrophil percentage (> 80%) | Section 2:4, Question 3 |
| Elevated Synovial WBC (> 3,000 cells / µL) | Section 2:4, Question 3 |
| Elevated ESR (> 30 mm/hr) | Section 2:4,Question 1 |
| Elevated CRP (> 10 mg/L) | Section 2:4, Question 1 |
| Elevated synovial alpha-defensin | Section 2:4, Question 7 |
| Cloudy fluid | Section 2:3, Question 3 |

PMN, polymorphonuclear leukocyte; WBC, white blood cell; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein

**TABLE 3. Clinical scenarios of the ICM diagnostic criteria in practice**

| # | Scenario | Definition |
|---|---|---|
| 1 | Painful shoulder arthroplasty:<br>• Positive aspirate culture (*C. acnes*): 3 points<br>• 1/5 intraoperative cultures positive (*C. acnes*): 1 point<br>• Humeral loosening: 3 points | Probable PJI |
| 2 | Painful shoulder arthroplasty:<br>• No aspirate completed<br>• Persistent unexpected wound drainage: 4 points<br>• 2/5 intraoperative cultures positive (*C. acnes*): 1 + 3 = 4 points | Probable PJI |
| 3 | Painful shoulder arthroplasty:<br>• Dry aspirate<br>• 2/5 intraoperative cultures positive (MSSA)<br>• Elevated ESR<br>• Elevated CRP | Definite PJI |
| 4 | Painful shoulder arthroplasty:<br>• Well-fixed components<br>• 2/5 intraoperative cultures positive (*C. acnes*): 1 + 3 = 4 points<br>• All other tests negative | Possible PJI |
| 5 | Painful shoulder arthroplasty:<br>• Persistent unexpected wound drainage: 4 points<br>• 1/5 intraoperative cultures positive (*C. acnes*): 1 point<br>• All other tests negative | Unlikely PJI |
| 6 | Painful shoulder arthroplasty:<br>• Persistent unexpected wound drainage: 4 points<br>• 1/5 intraoperative cultures positive (MSSA): 3 point<br>• All other tests negative | Probable PJI |

CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; MSSA, methicillin-sensitive *S. aureus*

ment of "infection" at the time of revision shoulder arthroplasty. We searched for all studies published in English using the terms (("revision" OR "failed") AND "shoulder" AND ("arthroplasty" OR "replacement")) limited to dates between January 1, 1996 and February 3, 2018.

A total of 2,354 studies were identified. We reviewed the titles and abstracts of all studies and excluded studies that (1) included patients with shoulder infection without arthroplasty, (2) reported on patients with positive cultures not considered infection or that were "unexpected," as a strict definition of infection in these studies was not applied, or (3) included patients with arthroplasty of joints other than the shoulder. The reference lists for all included studies were searched for any additional references and three references were added to our list. A total of 25 studies met inclusion criteria and were included in the final analysis.

## Data Collection

Relevant data were extracted from the selected publications, including the definition of infection used by the authors and the components it involved. Factors involved in the definition of infection included (1) clinical symptoms (erythema, sinus tract formation, drainage, systemic symptoms), (2) preoperative laboratory serology, (3) radiologic tests for infection, (4) preoperative aspiration laboratory results, (5) preoperative aspiration culture results, (6) intraoperative frozen section results and (7) intraoperative culture results.

## Results

See Appendix A, Table 1 below. An explicit statement describing how infection was defined was not present in 6 of 25 studies. A classification system was used in 5 of 25 of the studies, including three that utilized the Musculoskeletal Infection Society definition described by Parvizi et al. [2], one that utilized a definition reported by Spangehl et al. [12] for total hip arthroplasty, and one that utilized the classification described by Grosso et al. [13]. The remaining 14 studies used author-defined combinations of clinical symptoms, laboratory tests, radiographic characteristics, findings on aspiration, and results of cultures of specimens harvested at the time of revision.

## Workup for Periprosthetic Infection

Utilization of clinical signs and symptoms, preoperative serology, radiographic loosening and preoperative aspiration to workup and define infection was highly variable in the studies reviewed (Table 1). Of the 19 studies that provided a definition for infection, all used clinical examination findings as part of their definition, 14 used serum laboratory results, 6 utilized preoperative shoulder joint aspirate laboratory values, 10 used an intraoperative gram stain or frozen section and 6 used radiographic findings to aid in diagnosis. While all studies performed either preoperative aspiration or intraoperative tissue sampling for culture, intraoperative culture results were utilized in the definition of infection in only 10 studies.

**APPENDIX A: TABLE 1. Definition of infection in included studies**

| Author | Year | Definition Provided | Clinical Exam | Serum Lab Values | Aspirate Values | Aspirate Culture | Surgical Specimen Culture | Intraoperative Frozen / Gram Stain | Radiographic Findings |
|---|---|---|---|---|---|---|---|---|---|
| **Previously described criteria** | | | | | | | | | |
| Ghijselings [14] | 2013 | "criteria proposed by Parvizi et al." | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | X |
| Grubhofer [15] | 2018 | "according to the Musculoskeletal Infection Society (MSIS) PJI criteria" | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | X |
| Jacquot [16] | 2015 | "according to the Musculoskeletal Infection Society criteria" | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | X |
| Lee [17] | 2017 | "probable or definite infection as the criteria for periprosthetic shoulder infection [by Grosso et al.]" | ✓ | X | X | X | ✓ | ✓ | X |
| Romanò [18] | 2012 | "criteria established by Spangehl et al." | ✓ | ✓ | X | ✓ | ✓ | ✓ | X |
| **Combined definition** | | | | | | | | | |
| Achermann [19] | 2013 | "(1) visible purulence of a preoperative aspirate or intraoperative periprosthetic tissue, (2) presence of a sinus tract communicating with the prosthesis, (3) microbial growth in a preoperative joint aspirate, intraoperative periprosthetic tissue or sonication fluid of the removed implant, or (4) synovial fluid with > 1,700 leukocytes/ul or > 65% granulocytes." | ✓ | X | ✓ | ✓ | ✓ | X | X |
| Amaravathi [20] | 2012 | "based on a combination of symptoms, laboratory tests, and findings of physical examinations such as draining sinus, radiological evidence of loosening of prosthesis, and analysis of intraoperative specimen." | ✓ | ✓ | X | X | ✓ | X | ✓ |
| Beekman [21] | 2010 | "clinical picture… swelling, redness, or a sinus… and laboratory tests… or fistula without altered laboratory tests" | ✓ | ✓ | X | X | X | X | X |
| Buchalter [22] | 2017 | "clinical, laboratory, radiographic, and operative evaluations" | ✓ | ✓ | X | ✓ | X | ✓ | ✓ |

**TABLE 1. Definition of infection in included studies (*Cont.*)**

| Author | Year | Definition Provided | Clinical Exam | Serum Lab Values | Aspirate Values | Aspirate Culture | Surgical Specimen Culture | Intraoperative Frozen / Gram Stain | Radiographic Findings |
|---|---|---|---|---|---|---|---|---|---|
| Coste [23] | 2004 | "1) the presence of a sinus; 2) serum leucocyte count; 3) erythrocyte sedimentation rate; 4) C-reactive protein (CRP); 5) preoperative and peroperative joint aspiration cultures and cultures of surgical specimens; 6) loosening of the components on standard radiographs and periosteal reaction; and 7) three-phase bone isotope scanning." | ✓ | ✓ | X | ✓ | ✓ | X | ✓ |
| Jawa [24] | 2011 | "combination of symptoms, physical findings, and laboratory tests" | ✓ | ✓ | X | X | X | X | X |
| Jerosch [25] | 2003 | "clinical symptoms associated with positive blood tests… intra-articular aspirates with WBC over 30,000 cells or positive bacterial growth" | ✓ | ✓ | ✓ | ✓ | X | X | X |
| Kelly [6] | 2009 | "associated skin erythema, wound drainage, or obvious purulence or tissue synovitis at the time of surgery… clinical aspiration yielding a positive Gram stain or culture was considered infected… positive intraoperative Gram stain or frozen section showing more than five polymorphonuclear leukocytes per high-powered field was considered infected." | ✓ | X | X | ✓ | ✓ | ✓ | X |
| Levy [26] | 2015 | "clinical evaluation, radiographs, and laboratory test results" | ✓ | ✓ | X | X | X | X | ✓ |
| Mahure [27] | 2016 | "combination of clinical, radiographic, and laboratory tests" | ✓ | ✓ | ✓ | ✓ | X | ✓ | ✓ |
| Sabesan [28] | 2011 | "clinical suspicion, positive intraoperative frozen sections, positive culture treated at an outside referring institution, positive preoperative aspiration cultures, or positive intraoperative tissue cultures" | ✓ | X | X | ✓ | ✓ | ✓ | X |
| Sperling [29] | 2001 | "patient's clinical course, the observation of purulence at the time of surgery, and a sinus that communicated directly with the joint" | ✓ | X | X | X | X | X | X |

**TABLE 1. Definition of infection in included studies (*Cont.*)**

| Author | Year | Definition Provided | Clinical Exam | Serum Lab Values | Aspirate Values | Aspirate Culture | Surgical Specimen Culture | Intraoperative Frozen / Gram Stain | Radiographic Findings |
|---|---|---|---|---|---|---|---|---|---|
| Stone [30] | 2017 | "history of previous infection, findings on physical examination (i.e., skin erythema, swelling, draining sinus), laboratory tests (white blood cell count, erythrocyte sedimentation rate, and C-reactive protein) when obtained, and positive intraoperative findings, including purulence, intraoperative frozen section showing more than 5 polymorphonuclear leukocytes per high-powered field for 5 fields, and cultures" | ✓ | ✓ | X | X | ✓ | ✓ | X |
| Weber [31] | 2011 | "...to substantiate the clinical suspicion, laboratory analysis and radiological examination with blood tests including CRP and WBC. In patients with fistula, microbiological swabs were taken before the procedure and in other patients the joint itself was aspirated. In the case of remaining doubt about the infection, an indium-labelled white blood cell scan was performed." | ✓ | ✓ | X | ✓ | X | X | ✓ |
| **No clear definition provided** | | | | | | | | | |
| Braman [32] | 2006 | "No objective grading criteria were used." | | | | | | | |
| Ince [33] | 2005 | None | | | | | | | |
| Klatte [34] | 2013 | None | | | | | | | |
| Ortmaier [35] | 2014 | None | | | | | | | |
| Strickland [36] | 2008 | No explicit definition | | | | | | | |
| Zavala [37] | 2012 | None | | | | | | | |
| Overall | ✓= Component of definition | | 19 | 14 | 6 | 12 | 11 | 10 | 6 |
| | X = Not considered | | 0 | 5 | 13 | 7 | 8 | 9 | 13 |

This search methodology, results and table have been adopted and updated from Hsu et al. [1].
CRP, C-reactive protein; MSIS, Musculoskeletal Infection Society; PJI, periprosthetic joint infection; WBC, white blood cell

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# 2.4. DIAGNOSIS: INFLAMMATORY MARKERS

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## QUESTION 1: What is the role for serum erythrocyte sediment rate (ESR), C-reactive protein (CRP), or white blood cell (WBC) count in the evaluation of a shoulder arthroplasty for periprosthetic joint infection (PJI)?

**RECOMMENDATION:** Serum ESR, CRP or WBC count have poor sensitivity for the diagnosis of shoulder PJI. Although they should be obtained as part of a standard workup for infection, normal values do not rule out infection.

**LEVEL OF EVIDENCE:** Limited

**DELEGATE VOTE:** Agree: 96%, Disagree: 4%, Abstain: 0% (Unanimous, Strongest Consensus)