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Development of Diagnostic Quality Metrics for Prosthetic Joint Infection

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ABSTRACT

Although well-accepted clinical practice guidelines exist for the diagnosis of prosthetic joint infection (PJI), little is known about the quality of diagnosis for PJI. The identification of quality gaps in the diagnosis of PJI would facilitate the development of care structures and processes to shorten time to diagnosis and reduce the significant morbidity, mortality, and economic burden associated with this condition. Hence, we sought to develop valid clinical quality measures to improve the timeliness and accuracy of PJI diagnosis. We convened a nine-member multidisciplinary national panel of PJI experts including orthopedic surgeons, infectious disease specialists, an emergency medicine physician, and a patient previously treated for PJI to review, discuss, and rate the validity of proposed measures using a modification of the RAND-UCLA appropriateness method. In total, 57 permutations of six proposed measures were rated. Populations considered to be at high enough risk for PJI that certain care processes should always be performed were identified by the panel. Among the proposed quality measures, the panel rated five as valid. These novel clinical quality measures could provide insight into care gaps in the diagnosis of PJI.

Keywords: prosthetic joint infection, quality, quality measurers, diagnosis

Introduction

Prosthetic joint infection (PJI) is one of the most morbid and costly complications of total hip and knee replacement. Prosthetic joint infection is associated with high mortality,[1] decreased quality of life,[2] and worsened functional outcomes.[2] The incidence of PJI is projected to climb in parallel with the rising worldwide utilization of arthroplasty and the markedly increasing number of people alive and aging with joint replacements.[3] Well-accepted clinical practice guidelines (CPGLs) exist on how to establish a diagnosis of PJI.[4,5] However, systemic assessment of the quality of diagnostic care delivered by physicians and health systems in the setting of suspected or confirmed orthopedic infection remains unexplored. There exist no validated measures to assess the quality of care related to the diagnosis of PJI. Hence, we sought to develop valid clinical quality measures to improve the timeliness and accuracy of PJI diagnosis to facilitate eventual improvements in the health of patients with PJI.

Clinical quality measures (CQMs) quantify the occurrence and outcomes of needed care processes. An understanding of care gaps can facilitate the development of targeted quality improvement programs which, when implemented, should improve the health of populations. Electronic CQMs (eCQMs) specifically leverage the electronic health record (EHR) to assess the quality of healthcare provided. Electronic CQMs have the potential to improve the measurement of clinical quality by incorporating information found in EHRs.[6] At the same time, eCQMs reduce the administrative burden of quality measurement by eliminating the need for chart abstraction.[6] Finally, when embedded within the EHR, eCQMs can be constructed to monitor quality continuously and provide best practice alerts as to when specific care processes should be provided to establish a diagnosis.

As a first step toward developing a set of eCQMs about the quality of PJI diagnosis, we convened a multidisciplinary expert panel to rate and revise clinical indicators or concepts of quality that will

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Work for this project was performed at Hospital for Special Surgery, New York, NY and at Mathematica, Cambridge, MA.

Because this is a quality improvement project, the human subjects review committee at our institution did not require/decline to review.

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subsequently be used to specify and test eCQMs. We assessed whether we could define (1) a discrete set of necessary care processes that should be performed for almost all patients diagnosed with PJI; (2) discrete populations at high risk for PJI based on presenting signs and symptoms, test results, or the performance of certain procedures; (3) specific care processes that should be performed for almost all patients who are at high risk for PJI; and (4) valid clinical quality measures about the diagnosis of PJI. These eCQMs are intended to assess minimal measurable standards of care broadly applicable across wide variations of PJI clinical presentations, healthcare resources, and EHR systems.

Methods

Study Design

We used a modified version of the RAND/UCLA Appropriateness Method,[4,5] previously used to develop quality indicators[7] (Figure 1).

Development of Draft Process Indicators

Based on existing CPGLs-related literature and expert opinion, the investigators proposed six draft quality indicators across four domains.

The first domain, "completion of preoperative and intraoperative testing," included the following two measures: one examining preoperative diagnostic bundles completed and one examining intraoperative diagnostic bundles. The second domain, "screening for PJI among high-risk patients," included the following two definitions of high-risk populations: one included patients presenting with certain signs and symptoms of PJI and the other patients undergoing revision surgery. The other two domains, "identification of pathogens before surgery" and "involvement of an infectious disease specialist," each included one indicator. Variations of detailed specifications regarding each measure element were developed resulting in 57 permutations of the proposed measures (see Appendix, Supplemental Digital Content 1, **http://links.lww.com/JHQ/A200**). To refine the measure specifications to be as precise as possible, many of the proposed indicators varied slightly or contained different permutations of a group care processes. For example, the panel rated both whether patients who were diagnosed with PJI should have had (1) serum erythrocyte sedimentation rate (ESR) AND a serum C-reactive protein (CRP) and whether they should have had (2) a serum ESR OR a CRP within the 3 months before surgery.

Investigators developed potential quality indicators from existing guidelines, review criteria, and expert opinion. Most of the quality indicators were constructed in an "IF-THEN" format. The "If" part of the statement refers to the clinical presentation of persons to whom the indicator applies while the "Then" portion refers to the process of care that should or should not be applied under these circumstances. For example: "IF a patient was diagnosed with PJI of the hip or knee and underwent surgery, THEN a joint aspiration including cell count and culture should have been performed prior to surgery." This list of potential indicators was then presented to the expert panel for formal assessment of validity.

Review of Scientific Literature

We assessed relevant guidelines and definitions for diagnosing PJI including the Infectious Diseases Society guidelines released in 2011,[8] the Musculoskeletal Infection Society (MSIS) definition developed in 2011[9] and updated in 2018[10] as a scoring algorithm, the American Academy of Orthopaedic Surgeons algorithm released in 2013[11] and clinical guidelines released in 2019,[12] and the International Consensus Meeting (ICM) on Musculoskeletal Infection recommendations released in 2018.[13] A literature review was conducted using PubMed and Cochrane Library to identify any significant new literature not reviewed by the MSIS, American Academy of Orthopaedic Surgeons (AAOS), or at the ICM. After reviewing the guidelines and new literature, we prepared a summary detailing each of the quality indicators with corresponding recommendations from each guideline and key studies that guided those recommendations. We sent each panelist the proposed quality indicators and the summary of CPGLs and key studies.

Expert Panel

We convened a 9-member multidisciplinary panel of orthopedic surgeons, infectious disease specialists, an emergency medicine physician, and a patient previously treated for PJI to consider the proposed measures (Table 1). All panelists completed a disclosure form that detailed any financial or intellectual relationships that could be an actual or perceived conflict with this study. These disclosures were made available to the entire expert panel and discussed at the start of the first panel meeting.

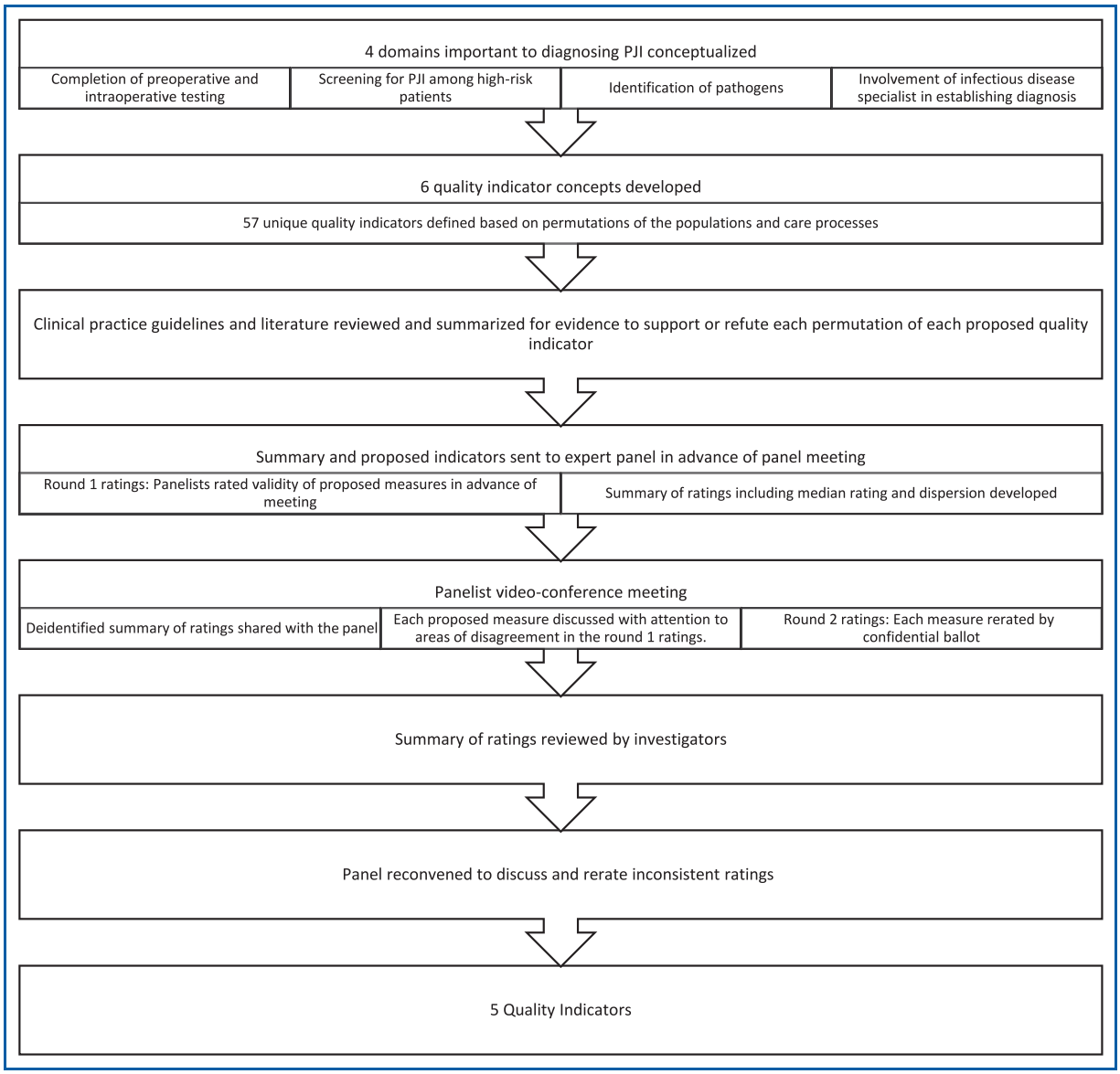

Figure 1. Overview of methods used to construct quality indicators of the diagnostic process for prosthetic joint infection (PJI).

To assess the expert opinions of the panelists, we used a modified version of the RAND/UCLA Appropriateness Method.[4,5] Panelists were asked to anonymously rate each element on a risk-benefit scale of 1–9 in two rounds with a virtual group discussion conducted between rounds. Each panelist has equal weight in determining the final ratings. The reproducibility of the RAND/UCLA Appropriateness Method is consistent with that of well-accepted diagnostic tests, such as the interpretation of coronary angiography and screening mammography.[14] It also has content, construct, and predictive validity.[5,15]

In this application of the method, we asked the panelists to assess the validity of each proposed indicator on a scale of 1–9, in which 1 was "definitely not valid" and nine was "definitely valid." We considered an indicator to be valid if (1) adequate scientific evidence or professional consensus supported a link between the process specified by the indicator and accurate diagnosis of PJI; (2) a physician or hospital with high rates of adherence to the indicator would be considered to be following standard care in diagnosing PJI; and (3) the physician or hospital could influence adherence to the indicator.

Table 1. Multidisciplinary Expert Panel

Panelists	Specialty	Institution
K. Keely Boyle, MD	Orthopedic Surgery	Buffalo General Medical Center
Barry D. Brause, MD	Orthopedic Surgery	Hospital for Special Surgery
Laura Certain, MD, PhD	Infectious Disease	University of Utah
Gregory Crooke, MD	Patient Representative	
Angela Hewlett, MD, MS	Infectious Disease	University of Nebraska
Javad Parvizi, MD	Orthopedic Surgery	Rothman Institute
Sandra Schneider, MD, FACEP	Emergency Medicine	American College of Emergency Physicians
Bryan Springer, MD	Orthopedic Surgery	OrthoCarolina
Aaron Tande, MD	Infectious Disease	Mayo Clinic

Each panelist was instructed to rate each potential quality indicator for validity and return the ratings to us before the virtual meeting. We prepared summaries of these ratings for distribution at the panel meeting. At the virtual panel meeting, each quality indicator was discussed in turn; the discussion focused on the evidence (or lack thereof) supporting or refuting the indicator and the prior rankings of the panelists. Panelists had in front of them the summary of the panel's first-round ratings and a confidential reminder of their own previous rating. The indicators were reworded or otherwise clarified to better fit the expert panel's clinical judgment. For example, the initial ratings sheet gave an option to rate the importance and validity of requiring a number of different individual tests. The panel requested an option to rank ESR and CRP as a group, i.e., require both ESR and CRP testing.

After the discussion, each indicator was reranked for validity. Analysis of the final-round rankings was similar to that used in past applications of the RAND/UCLA Appropriateness Method.[5,16] We used the median panel rating and measure of agreement to categorize the validity of the indicators. We considered disagreement among a panel to occur when at least three members of a panel judged the indicator to be in the highest tertile of validity (the indicator received a rating of 7, 8, or 9) and three members rated the indicator to be in the lowest tertile of validity (rating of 1, 2, or 3).[5] All indicators with panel disagreement were rejected.

In a follow-up meeting, we reviewed all of the indicators with a median validity rating of seven or greater (without disagreement) and assessed whether these indicators should be modified or deleted. We reviewed the final set of indicators for consistency across measures, coherence, and content validity. The final set of indicators therefore resulted from an initial set that was selected by content experts in the field based on CPGLs and supporting evidence.

Because this is a quality improvement project, the human subjects review committee at our institution did not require and declined to review.

Results

Within four domains six measures concepts, 57 permutations of the proposed indicators were presented to an expert panel for validity assessment (see Appendix, Supplemental Digital Content 1, **http://links.lww.com/JHQ/A200**). The panel rated 23 of the unique permutations as valid and 12 as not valid. For the remaining 22 permutations, there was disagreement (7) or uncertainty (15) among the panelists as to the validity of the proposed measure element.

Among 11 care processes for PJI diagnosis that were considered, the expert panel rated seven as necessary to establish a diagnosis of PJI: in the preoperative period, serum ESR, serum CRP, and joint aspiration including cell count, differential of cell count, culture of aspirate, and antibiotic sensitivity of the culture; and intraoperatively ≥3 tissue samples which were sent for culture and held long enough to detect anaerobic organisms. Alpha defensin levels, leukocyte esterase (LE) test strips, polymerase chain reaction (PCR) tests to identify

organisms, and Gram stain from joint aspirations were not rated as necessary. The use of intraoperative swab cultures (as opposed to tissue cultures) and obtaining fewer than three intraoperative tissue samples were deemed insufficient (Table 2).

Populations considered to be at high enough risk for PJI that certain care processes should always be performed to evaluate for PJI included those undergoing revision arthroplasty, as well as patients with implant loosening or bone resorption and osteolysis, pain localized to a prosthetic hip or knee, and patients with at least two of the following: joint swelling, erythema, or warmth (Table 2).

Care processes deemed necessary for high-risk patients included serum ESR and serum CRP and for all except those undergoing revision arthroplasty, a joint aspiration including cell count, differential of cell count, and culture of aspirate held long enough to detect anaerobic organisms; care processes rated as not necessary included alpha defensin, LE strip tests, PCR tests to identify organisms, and Gram stain from joint aspirations (Table 2). The performance characteristics for these diagnostic tests were summarized (Table 3).[17-23]

The 23 unique permutations consolidated into five indicators (Figure 2) focused on: (1) preoperative PJI testing among patients who underwent surgery for PJI, (2) intraoperative diagnostic testing in patients undergoing surgery for PJI, (3) diagnostic workup for PJI among high-risk patients, (4) evaluation for PJI among patients undergoing revision arthroplasty, and (5) consultation of an infectious disease consultant for the management of PJI. Indicators requiring the identification of organisms before surgery were not rated as valid.

Limitations

Adapting the measures for use within varied EHR systems without bias and with accuracy may be difficult, and careful analysis of data from diverse sites is needed to explore whether differences are related to quality of delivered care versus the quality of extracted data. Although a strength of our approach is that our proposed metrics are based on CPGL and our expert panel, these process measures may require updating as our ability to diagnose and treat PJI improves over time. The lack of standardization of EHRs, and the possibility that patient data may reside in different EHRs as they transition between inpatient and outpatient care, may also challenge the feasibility of these measures.

Discussion

Assessing the quality of the diagnostic workup remains a challenge throughout medicine, and electronic measures to augment traditional quality metrics represent an opportunity to advance the field. Prosthetic joint infections, which are devastating for patients and costly for payers, can present with diverse signs and symptoms and can be difficult to diagnose. Without adequate clinical suspicion, diagnosis can be delayed, and without prompt and adequate treatment, optimal outcomes are unlikely.

We aim to develop a validated method for the assessment of diagnostic quality throughout the preoperative and intraoperative course of management of patients with confirmed or possible PJI. In this stage of the project, indicators of quality were developed using review of relevant literature and CPGL. Current CPGLs describe care processes that should be considered. Although the panel ratings were consistent with current CPGLs, they represent a subset of these care processes that should always be performed as a minimal standard of care. Given the diversity of healthcare resources and approaches, the heterogenous nature of patients and their infections, and the variations of electronic documentation across systems, these indicators are intended to represent minimal and consistently measurable standards of care, rather than aspirational measures of ideal care delivery.

To the best of our knowledge, our project is novel to orthopedics and could help optimize outcomes and limit financial burdens associated with this serious condition. Broadly within orthopedics, a broad variety of quality measures have been developed.[24-26] A smaller portion of these have been clearly shown to improve care[27] and lower costs.[27] Within arthroplasty, a minority of CQM are outcome measures (for example, the rate of readmission among total knee arthroplasty patients) and a majority are process measures (for example, the use of appropriate thromboprophylaxis); in a recent assessment of all available quality measures in arthroplasty, the only CQM including a reference to infection was an outcome measure assessing the all-cause rate of return to the operating room after an index procedure.[25] Published arthroplasty-related process eCQMs measure the rate of respiratory depression and other complications after arthroplasty,[28] but quality measures specifically assessing the care delivered to patients with possible or confirmed PJI have not been developed.

The 40% of indicators that were rated as valid were rated as such not only because they were considered clinically valid but because they were considered diagnostically necessary. By contrast, indicators could

Table 2. Panel Ratings on Populations That Should be Evaluated for PJI and the Necessary Care Processes That Should be Performed

Populations	PJI evaluation always indicated (Y/N)	Care processes	Necessary to diagnose PJI (Y/N)
Patients undergoing surgery for PJI	Y	Preoperatively	
		Serum ESR Serum CRP Joint aspiration and cell count and differential culture, aerobic and anaerobic antibiotic sensitivity alpha defensin LE strip test PCR to identify microbe	Y Y Y Y Y Y N N N
		Intraoperatively	
		≥3 tissue samples which were sent for culture and held for appropriate time to identify anaerobic organisms	Y
		≥1 tissue sample that was sent for culture and held for appropriate time to identify anaerobic organisms	N
Patients with prior TKA/THA AND ≥2 of the following: Joint swelling OR joint erythema OR joint warmth Implant loosening, bone resorption or osteolysis Pain localized to arthroplasty for ≥ 6 weeks	Y Y Y	Serum ESR Serum CRP Joint aspiration and cell count and differential culture, aerobic and anaerobic antibiotic sensitivity alpha defensin LE strip test PCR to identify microbe	Y Y Y Y Y Y N N N
Patients undergoing revision arthroplasty	Y	Serum ESR Serum CRP Joint aspiration and cell count and differential culture, aerobic and anaerobic antibiotic sensitivity alpha defensin LE strip test PCR to identify microbe	Y Y N N N N N N N

CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; LE = leukocyte esterase; N = no; PCR = polymerase chain reaction; PJI = prosthetic joint infection; THA = total hip arthroplasty; TKA = total knee arthroplasty; Y = yes

be rejected for several reasons, including insufficient evidence linking the proposed indicator with accurate diagnosis of PJI, competing indicators addressing the same concept, the perception that the data to score the indicator were too difficult to collect, and that certain diagnostic tools may not be widely available.

We used an explicit method to derive process-related eCQM for the diagnosis of PJI based on literature review, CPGL, and expert opinion. Indicators include preoperative and intraoperative diagnostic testing on patients at increased risk of infection and those with confirmed PJI. These

Table 3. Performance Characteristics of Diagnostic Tests for PJI

	Sensitivity	Specificity	Source
Serum ESR	0.75 (Confidence interval [CI] 0.72–0.77)	0.70 (CI 0.68–0.72)	17
Serum CRP	0.88 (CI 0.86–0.90)	0.74 (CI 0.71–0.76)	17
Synovial leukocyte count	0.81–0.95 (range)	0.91–0.100 (range)	18
Synovial leukocyte differential	0.81–0.92 (range)	0.69–0.90 (range)	18
Synovial fluid culture	0.06–0.96 (range)	0.85–1.00 (range)	19
Alpha defensin	0.98 (CI 0.95–1.00)	0.96 (CI 0.94–0.98)	20
LE test strips (synovial fluid)	0.81 (CI 0.49–0.95)	0.97 (CI 0.82–0.99)	21
PCR testing	0.70 (CI 0.67–0.73)	0.93 (CI 0.91–0.94)	22
Synovial gram stain	0.19 (0.12–0.27)	1.00 (0.99–1.00)	23

CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; LE, leukocyte esterase; PCR = polymerase chain reaction; PJI = prosthetic joint infection.

proposed eCQMs may be useful in future assessments of the care delivered to arthroplasty patients. Further assessment of the feasibility and reliability of these measures across multiple sites is warranted.

Conclusions

A subset of the care processes detailed in CPGLs to establish a diagnosis of PJI was considered necessary among specific populations. These processes and populations establish the foundation for five novel clinical quality measures that could provide insight into care gaps in the diagnosis of PJI.

Implications

Application of these measures will inform whether care gaps exist for PJI and how large they are. Assuming care gaps exist, quality improvement

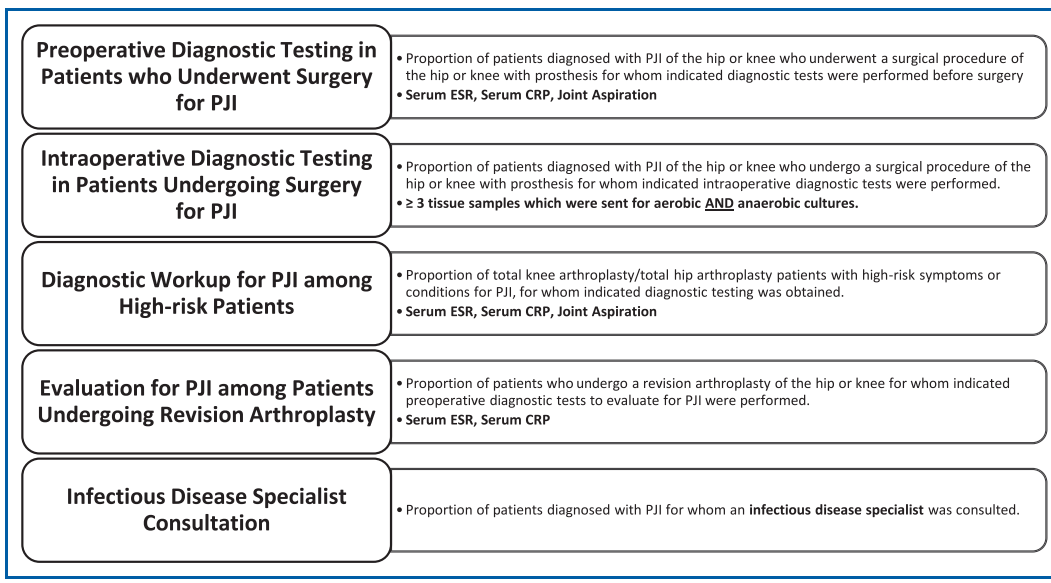

Figure 2. Quality indicators for diagnosing prosthetic joint infections (PJIs) rated as valid by the committee.

activities for the diagnosis could significantly reduce the morbidity and cost of PJI by reducing time to diagnosis and the effectiveness of therapy.

Authors' Biographies

Andy O. Miller, MD, is an Associate Attending Physician, Associate Professor of Clinical Medicine, and Chief of the Division of Infectious Diseases at Hospital for Special Surgery in New York, NY. Dr. Miller provides clinical care to patients with musculoskeletal infections and helps to develop and coordinate administrative, research, and educational activities to improve patient safety and optimize infection outcomes in orthopedics and rheumatology.

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