ICM ICM 2025 Question B12: "What are the minimum data set for studying orthopaedic infections?"

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RESPONSE/RECOMMENDATION: There appears to be marked variation in the reporting of data regarding orthopaedic infections, and as a result there is limited comparability across the orthopaedic literature. Future studies should strive to include a minimum of 300 patients per comparison group with 1-year minimum follow-up and key data on patient characteristics (e.g., systemic and extremity compromising factors), operative factors (e.g., indication, need for transfusion, type of implants used), diagnostic criteria (e.g., serum and synovial fluid studies, operative cultures), and postoperative outcomes (e.g., patient-reported outcome measures).

LEVEL OF EVIDENCE: Expert Opinion

DELEGATE VOTE: Agree: [% vote], Disagree: [%], Abstain: [%]

RATIONALE: Infection remains a major cause of morbidity and mortality in patients undergoing orthopaedic procedures [1]. In recent years, we have witnessed a surge in the use of large data sets such as administrative datasets to study orthopaedic infections. While these datasets hold large numbers of patients, they often lack the granularity necessary to study how different infection management protocols impact treatment outcomes in orthopaedics [2-6]. Additionally, there is still marked variability in the reporting of registry data, resulting in major challenges when both aggregating data or comparing results across different studies [7]. In order to appropriately investigate orthopaedic infections, a clearer definition of the minimum data set is paramount to ensuring the collection of accurate clinical data that is translatable to meaningful improvements in patient care [8,9]. This can be stratified into preoperative, intraoperative, and postoperative variables. Given that infection rates range from roughly 1-5% following orthopaedic surgeries with implants, it may be reasonable to propose that a minimum patient sample size of 300 patients per comparison group is needed to reduce the likelihood of underpowered analyses and type II errors [10].

Host optimization is an important factor preoperatively with regard to the prevention and treatment of orthopaedic infections [11-14]. The McPherson classification has long been used in patients with hip and knee periprosthetic joint infection (PJI), which highlights the importance of infection type (early postoperative, hematogenous, or late chronic), systemic host compromising factors, and local extremity compromising factors [15,16]. Patient characteristics such as obesity, diabetes, inflammatory arthritis, immunosuppressive medications, anemia, renal disease, malnutrition, mental health disorders, nicotine use, alcohol abuse, and human immunodeficiency virus (HIV) infection status are also well recognized modifiable risk factors in this patient population [17-19]. Preoperative laboratory values such as hemoglobin A1c, 25-hydroxyvitamin D, albumin, prealbumin, total protein, total lymphocyte count, iron, and transferrin have also been shown to be predictors for infection in patients undergoing orthopaedic procedures [20-23]. It is also important to identify whether a patient has had prior surgery, has a history of infection at the same surgical site, or is being administered chronic antibiotic suppression. At a minimum, patient age, sex, body mass index, relevant surgical history, and compromising medical comorbidities must be reported. Including socioeconomic factors individually or through a comprehensive approach such as the Area Deprivation Index (ADI) in the United States, large datasets studying infection can reveal critical disparities in healthcare utilization and recovery. Addressing these factors is essential to beginning to understand and mitigate the influence of socioeconomic disadvantage on orthopaedic surgery postoperative complications and infection [24-30].

Operative characteristics have also been shown to be a factor in the development of orthopaedic infections [13,31-33]. Some technical aspects of surgery, such as soft tissue handling, wound management, operating room traffic, and cleaning of instruments, are difficult to standardize and report. However, other variables, such as surgical indication, operative time, estimated blood loss, need for transfusion, general type of implants used (e.g., primary versus revision components), and length of stay, are routinely recorded in the electronic medical record and should be included in the minimum data set for orthopaedic infections.

Serum and synovial fluid laboratory studies, in combination with operative findings and cultures, are used to diagnose orthopaedic infections [34]. Microbiology data and pathogen identification, when available, are valuable and may impact the medical and surgical treatment plan [35,36]. Studies should be transparent and report the actual data from which the diagnosis of an orthopaedic infection is made (e.g., utilizing the 2018 International Consensus Meeting or the 2021 European Bone and Joint Infection Society criteria for hip and knee PJI) [37,38].

Lastly, there is a paucity of literature on the postoperative criteria used to define treatment success for orthopaedic infections [39]. The outcomes for the management of orthopaedic infection include infection control with no continued antibiotic therapy, infection control with suppressive antibiotic therapy, retained spacer, need for reoperation, and death. The need for reoperation could be for aseptic or septic reasons, and the time to reoperation or death is important to note, as reoperation or death less than 1 year after the treatment of an orthopaedic infection is more likely to represent a treatment failure [40,41]. The minimum follow-up to report treatment outcomes for orthopaedic infections is unknown, but recent literature has suggested a minimum one-year follow-up after treatment for hip and knee periprosthetic joint infection and fracture-related infection and up to 5-years to determine PJI ‘remission’ [42-44]. With the current emphasis on patient-centered and value-based healthcare, patient-reported outcome measures (PROMs) have become an important component [45,46]. There are general health and condition-specific PROMs, which can be combined to paint a more complete picture of the overall outcome, as infection eradication does not always equate to patient satisfaction. Thus, patients should be followed for a minimum of one year following treatment of an orthopaedic infection with PROMs being tracked preoperatively and postoperatively. A standardized approach to reporting PROMs is critical in this context to ensure that the data collected reflects true clinical relevance. Orr et al. emphasize that a value-driven healthcare model requires accurate analysis and reporting of PROMs to identify patients who don’t meet clinical thresholds. Using the "clinical relevance ratio," which assesses outcomes based on MCID and PASS, provides an unbiased measure of treatment effectiveness by focusing on the proportion of patients achieving meaningful improvements, thus enhancing the utility of PROMs in assessing satisfaction and success in orthopaedic care [47].

Conclusion:

In summary, with the current knowledge and available evidence regarding orthopaedic infections, it is reasonable to propose that the aforementioned variables comprise the minimum data set for studies related to orthopaedic infection (**Table 1**). Moving forward, new literature should strive to report this data to maximize generalizability and comparability across the orthopaedic literature.

Table 1. Criteria for the minimum data set to study orthopaedic infections.

Sample Size	300 patients per comparison group
Patient Factors	Age
	Sex
	Body mass index
	Relevant surgical history
	Host compromising factors (e.g., diabetes, autoimmune disease, immunosuppressive medication, renal disease, or malnutrition)
	Extremity compromising factors (e.g., soft tissue loss or vascular insufficiency)
	Socioeconomic factors (e.g., area deprivation index)
Surgical Factors	Surgical indication (e.g., elective vs traumatic)
	Operative time
	Estimated blood loss
	Need for transfusion
	Type of implants used (e.g., primary vs revision components)
	Length of stay
Diagnostic Criteria	Serum laboratory studies (ESR, CRP)
	Synovial fluid analysis (if applicable)
	Operative culture data
Outcomes	Minimum 1-year follow-up
	General health and condition-specific PROMs

CRP = C-reactive protein, ESR = erythrocyte sedimentation rate, PROMs = patient reported outcome measures

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