PACT Study - Registration Template

Please complete the form and send to ukpactstudy@gmail.com

Clinical Audit Project Proposal form,

Audit Lead (can be either junior or senior PI)

Name:	**Division:** Surgery
Job Title:	**Specialty:** Trauma and Orthopaedics
Email:	**Bleep:**
Hospital:	

Title: *UK Prophylactic Antibiotics in Complex Trauma (PACT) Study: A national collaborative project on the use of prophylactic antibiotics in patients with a complex fracture of the lower limb.*

Project Team

PI	Name	Email Address	Job Title	Position
Senior PI				
Junior PI (1)				
Junior PI (2)				
Junior PI (3)				

Participation Details:
Trauma and Orthopaedics *Named Consultant*

Who in this area have you discussed and agreed this audit with?		
Name:	*Job Title:*	*Date agreed:*

Further details of the study can be found below:

PACT Study - Study details for Registration

The below is a summary of information for the audit/service evaluation that you may use for registration purposes. Additional information including data collection and study protocol can be found on the website.

Aim
The PACT Study (Prophylactic Antibiotics in Complex Trauma) is a multicentre prospective service evaluation that aims to understand and explore the current treatment strategies patients with a complex fracture receive.

Objectives
1. Identify hospitals treating patients with a complex fracture.
2. Describe the prophylactic antibiotic prescribing strategies in patients with a complex fracture.
3. Estimate the Rate of SSI in patients with a complex fracture.
4. Identify centres willing to take part in a feasibility study using antibiotic bone graft substitute as an adjunct to standard treatment.

Study Design
Multicentre national collaborative collecting data prospectively using a centralised database.

Methods
Any hospital in the UK that admit and treat patients with a complex fracture can be included in this study. A named consultant supervisor will be required at each participating centre and the project will need to be registered with the local audit/service evaluation department. Data will be collected prospectively for all patients admitted to each hospital with a complex fracture. Patient demographics will be documented as will the co-morbidities. Fracture characteristics will be described using the AO fracture classification, for periarticular fractures, or the OTS classification, for open fractures. The use of prophylactic antibiotics will be identified, and the method of delivering antibiotics will be described. Evidence of Surgical Site infection (SSI) and/or Fracture Related Infection (FRI) within 30 days will also be recorded, as will the willingness of different hospitals to participate in a clinical trial using antibiotic bone graft substitute.

Data Collection
Data will be collected prospectively. Each participating site will record their data on REDCap. Information on what data items will be captured is available on the study website.
As we are not collecting patient identifiable information, we advise hospitals to keep a log of the hospital or NHS number and the corresponding study participant number each, so that no duplicate records are recorded.

Local Registration
Any UK hospital treating patients with a complex fracture can take part in this study. The study will need to be registered through the local audit department.

Eligibility Criteria
Inclusion criteria:

- Age 16 years or older
- Sustained a complex fracture of the lower limb:
    - Open fractures of the tibia
    - Proximal tibia fractures (AO/OTA 41)
    - Distal tibia fractures (AO/OTA 43)

Analysis
Data will be summarised descriptively and will provide insight into complex fracture epidemiology across the UK. From this we will be able to identify hospitals that admit and treat underrepresented patient groups with a rural/urban mix and assess the willingness of these hospitals to take part in a trial using antibiotic bone graft substitute as an adjunct to standard practice. Additionally, we will identify the current antibiotic prescribing strategies patients with complex fractures are currently receiving which will provide a baseline understanding of variability between centres and identify hospitals that are currently using adjuncts such as local antibiotics, antibiotic bone graft and antibiotic coated implants to reduce the risk of SSI.

Presentation
Following analysis, a data summary of the findings will be made available to all contributing institutions. Local presentation is recommended to identify the burden of complex fractures locally, the treatments these patients receive with regards to antibiotic prophylaxis and the risk of surgical site infection (SSI) and fracture related infection (FRI). The data shall be presented at regional and national orthopaedic meetings.

Costs
No local costs should be incurred through the routine collection of audit data against national standards.

Study background
Infections following the surgical management of fractures are catastrophic complications, significantly affecting patients' quality of life. The risk of infection is higher in patients with complex fractures, particularly complex fractures of the lower limb. Complex fractures of the lower limb are fractures that involve an articular surface (Pilon and Tibial Plateau) or those that are associated with significant soft tissue injury. There are some new techniques to reduce the risk of infection in this high-risk group, however, there remains a lack of high-quality evidence to support their use in clinical practice.

Standards
The primary objective of this project is to perform a national service evaluation to identify and describe the prophylactic antibiotic treatment strategies given to patients with a complex fracture of the lower limb. However, there are opportunities for hospitals to use the collected data to audit against national guidelines as described below.

National guidelines

Hospitals may use the collected data to audit against the following national guidelines:

Guidelines

- NICE guidelines: Surgical Site Infections: prevention and treatment
  - 1.2.12 – Give antibiotics prophylaxis to patients before clean surgery involving the placement of an implant.
  - 1.2.15 – Consider giving a single dose of antibiotics prophylaxis intravenously on starting anaesthesia. However, give earlier for operations in which a tourniquet is used.
- NICE guidelines: Assessment and Management of Complex fractures
  - 1.2.32 – Create a definitive management plan and perform initial surgery (temporary of definitive) within 24 hours of injury in adults (skeletally mature) with displaced pilon fractures.
  - 1.2.33 – If a definitive management plan and initial surgery cannot be performed at the receiving hospital within 24 hours of injury, transfer adults (skeletally mature) with displaced pilon fracture to an orthoplastic centre (ideally this would be emergency department to emergency department transfer to avoid delay)
- BOAST guidelines for Fracture related infection:
  - A trust should be able to demonstrate that is uses an agreed uniform set of standards for the prevention of implant related infection in trauma and elective orthopaedic surgery.
  - A trust must have a robust surgical site infection surveillance system.

Data collection Methodology

Case notes	Operation Notes	Images (XR/CT/MRI)	Medication chart	Electronic Patient Records (EPR)
✓	✓	✓	✓	✓

Further details

Patients presenting with a complex fracture of the lower limb will be screened and those that meet the eligibility criteria can be included in the study. Patient demographics and comorbidities will be recorded from patient notes. Radiographic images (Xray, CT, MRI) will be reviewed and used to identify the fracture classification. The use of prophylactic antibiotics will be identified from the operation note, anaesthetic chart, patient notes or medication charts and documented. We will also review patient notes and HSE for evidence of Surgical Site Infection (SSI) and Fracture Related Infection (FRI).