Service evaluation documents

1.1 Service evaluation protocol

DINOSAUR: Duration of Intravenous antibiotic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population.

Sponsor: University Hospital Southampton NHS Foundation Trust

Sponsor Code: RHM CHI 0639

NHS REC have advised that no formal approval is required for this service evaluation: committee comments are incorporated into study materials.

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1. Hypothesis and aims

Currently there is little international or UK consensus regarding the route or duration of antibiotic treatment for acute osteomyelitis (OM)/septic arthritis (SA) in children. Data regarding paediatric bone and joint infections in the UK are scarce and outdated. This service evaluation will be used to:

1. Assess current case load, disease spectrum & clinical practice in the diagnosis & treatment of OM/SA in secondary & tertiary UK care

2. Determine whether a randomised controlled trial to investigate shorter duration of intravenous antibiotic therapy for bone and joint infections in children is feasible in the future.

This will be achieved in conjunction with a future component of the study obtaining qualitative & quantitative data on:

a) willingness of clinicians to randomise to proposed protocol

b) willingness of patients & parents to be randomized

c) number of patients seen;

d) clinical stakeholder & consumer perception of relevant outcomes

2. Background

The text from pp5-14 was written for the HTA application but was published separately as http://adc.bmj.com/content/97/6/545 and is reproduced with permission from BMJ.

Osteomyelitis and Septic Arthritis in Children

Osteomyelitis (OM) is inflammation of the bone accompanied by bone destruction (1), usually due to bacterial infection. It is an acute process but if not treated effectively, the inflammation can become chronic, leading to the development of sequestrae and fistulae (2). Osteomyelitis and septic arthritis can both be divided into three types according to the source of the infection: haematogenous, secondary to contiguous infection and secondary to direct inoculation. Haematogenous OM can present acutely or as a more indolent, progressive process subacutely, with symptoms present for more than 2 weeks (3). In children

osteomyelitis most often affects long bones (femur 36%, tibia 33%, humerus 10%, pelvis 2.8%) (4). Single site infection is most common, but 5-20% of children have multifocal osteomyelitis (5). Septic arthritis (SA) is acute infection of synovial joints (6, 7), usually secondary to bacteraemia. The infection affects the synovial membrane and the joint space. In younger children, the capsule of the joint often extends to the metaphysis, which when the cortex is damaged can lead to septic arthritis secondary to osteomyelitis and vice versa. The epiphyseal growth plate can also be affected, causing growth discrepancies and long term disability or permanent joint destruction if the acute infection is not treated promptly (2).

The estimated incidence for both OM and SA arthritis in Western populations is between 5 to 12 cases per 100,000 children per year (2). Half of the children with acute haematogenous osteomyelitis are under the age of 5 (2, 7). Boys are 1.2-3.7 times more likely to be affected by osteoarticular infection (OAI) than girls (2). The incidence in Southampton from 1979-1997 was between 1.4 to 10.5 cases per 100,000 per year (8) and in Newcastle from 1991 to 1999 was 7 per 100, 000 for SA and 11 per 100, 000 for OM (unpublished data). Recent unpublished national data from England shows the admission rate for osteomyelitis in children 0-18 year of age has varied between 0.048 and 0.070 per 1000 child years (M. Sharland, personal communication). Subacute OM appears to be increasing over recent years (9), reported to be found in 5 per 100, 000 children in Norway (10). Neonatal infection can occur in preterm or term babies and is associated with a wider range of causative organisms (table 1, (11)) and potential complications. Neonatal vascular anatomy allows infection within bone to reach the growth plate or joint in 76%(12).

From the current literature, the pathogens implicated in paediatric bone and joint infections:

- commonly include *Staphylococcus aureus* (MSSA) (44-80%) (7, 13, 14) and *Kingella kingae* (14-50% (increased <36 months)) (7, 14-18);
- rarely include Methicillin-resistant *S. aureus* (MRSA) (40-50% in USA, rare in UK (19, 20)), Panton-Valentine Leukocidin (PVL) MSSA (21, 22), *Group A streptococci* (GAS) , *Group B streptococci* (GBS) (neonates) (11, 23), *Non-typeable Haemophilus spp*. (incidence unknown), *Haemophilus influenzae type b* (non-immunised or immunodeficient), *Escherichia coli* (neonates) (11, 23), *Streptococcus pneumoniae* (24), *Coagulase-negative staphylococcus* (subacute);
- very rarely (most in immunocompromised individuals) include *Pseudomonas aeruginosa* (usually inoculation injuries therefore > 1 year old), *Neisseria*

gonorrhoeae, *Neisseria menigitidis* (neonate, adolescent), *Mycobacterium tuberculosis* (older children as OAI develops 2 years from primary infection), *Salmonella spp.* (sickle cell disease) (25), *Bartonella henselae*, *Neisseria gonorrhoreae*, *Non tuberculous mycobacteria* (associated with defects of IFNg/IL12 pathway), *Klebsiella spp*, *Bartonella henselae*, *Fusobacterium* (often multifocal), *Aspergillus* and *Candida albicans* (neonate, damaged bone).

The pathogens most frequently seen according to age are:

- Neonate: GBS, MSSA, *Escherichia coli* and other gram negatives, *Candida alibicans*
- < 2 years: MSSA, *Kingella kingae*, *S. pneumoniae*, *Haemophilus influenzae type b* , *Non-typeable Haemophilus spp.*, *E. coli*, MSSA PVL
- 2-5 years MSSA, Kingella kingae, GAS, S. Pneumoniae, Haemophilus influenzae type b, Non-typeable Haemophilus spp., Pseudomonas spp., Coagulase-negative staphylococcus (subacute), MSSA PVL
- > 5 years MSSA, MSSA PVL

Clinical features

The clinical features of OM and SA are dependent on age, site of infection and type of disease. The diagnosis and management of osteoarticular infection in children should ideally be multidisciplinary, including paediatricians and orthopaedic surgeons with radiologists and microbiologists. The diagnosis of OM or SA is made on the basis of the clinical presentation, laboratory tests, imaging and where available microbiology results.

White Blood Cell Count, CRP and ESR

The white blood cell count (WBC) is an unreliable indicator of an OAI as in many cases it remains normal throughout the infection (26). The inflammatory markers erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) are more reliable, although normal values also do not exclude osteomyelitis (27). CRP levels are most sensitive (elevated in up to 98% of cases) (6, 7) but not specific for bone or joint infection. Two studies have shown that CRP increased and also decreased faster than ESR, predicting recovery with more sensitivity than the ESR or the white cell count (27, 28). Differences in the causative organism may also cause differences in the acute phase markers. Patients with osteomyelitis caused by PVL-expressing Staphylococcus aureus isolates had significantly higher mean values for ESR at admission, and higher maximum CRP, ESR and absolute neutrophil counts

at presentation compared with patients whose isolates were PVL-negative (22). Other markers remain unproven. In a small study, procalcitonin has not shown benefit over CRP (29).

Imaging

Imaging is of great importance in the diagnosis of acute osteomyelitis.

Where available, Magnetic Resonance (MR) Imaging with enhancement show the best results regarding sensitivity and specificity of diagnosis of both OM and SA (sensitivity 97% and specificity 92% (30, 31), sensitivity 97-100% in OM) (6)) However as young children often require a general anaesthetic to undergo an MR scan, and MR imaging is not immediately available in all UK centres, MR is not widely used in the UK in the initial diagnosis.

Technetium radionuclide bone scan (99mTc) also has high sensitivity and specificity in the diagnosis of OM (32), but due to the radiation burden is now used less often except in difficult cases and is not useful in discitis. In SA, bone scan may be used to exclude underlying OM following aspiration and commencement of empirical therapy. Bone scan is especially useful where there is a suspicion of multifocal disease, but may give false negative results in infancy, and sensitivity is reduced for the first 48 hours. New nuclear medicine technologies are available in some centres to combine bone scan with low dose CT (SPECT CT) which may be useful in increasing the resolution of nuclear medical images (33).

Plain radiographs are less helpful compared with other imaging techniques as osteolytic changes or periosteal elevation occur most often 10 to 21 days after the onset of symptoms (1, 7, 34). However, once apparent, the extent of bony change provides a good correlate to the severity of the disease. Plain radiographs also provide a baseline for comparison of subsequent change. Radiographic changes are frequently seen in subacute OM, but can be confused with malignancies such as Ewings sarcoma or osteiod osteoma (12). In SA, plain radiographs are of limited use. In discitis, lateral radiographs of the spine 2-3 weeks into the illness often will reveal disc space narrowing with erosion of the vertebral end plates of the contiguous vertebrae. In vertebral OM, radiographs initially show localised rarefaction of a single vertebral body then anterior bone destruction.

Ultrasound is useful in SA for identifying the presence of deep effusions and in OM for subperiosteal collections, but cannot differentiate between purulent and non-purulent material (6, 35).Ultrasound may also be used to distinguish infection from other causes of similar symptoms or to direct fine needle aspiration (36).

Computed tomography (CT) is most valuable for guided procedures, such as aspiration or drainage of the infected bone or joint (37). It effectively demonstrates air and sequestra and cortical destruction in chronic OM (35), but gives non-specific results in discitis.

Microbiological investigation

Identification of the pathogenic organism by culture should be attempted with samples preferably taken prior to starting antibiotic therapy, as where positive it allows targeted antibiotic therapy. Blood cultures, joint fluid (from aspiration), periosteal pus or bone biopsy can all be used. Samples from the infected bone or joint require an invasive procedure but are more likely to be positive (40- 50% positive) than blood cultures (9-22% positive) (14, 26). Yield is generally not high for identification of bacteria in children with OM (26), as unless therapeutic operative intervention is required, bone biopsy is infrequently necessary for diagnostic reasons alone.

New molecular techniques including PCR and broad-range 16s rDNA PCR (38, 39) have established the basis for more rapid and sensitive microbiological diagnosis (17), although these methods currently do not provide information on specific organism antibiotic resistance profiles.

Blood cultures (minimum 4 ml aerobic culture sample in older children, 2 ml in specific neonatal aerobic bottle (40)) should therefore be taken, and where available samples from infected bone or joint placed in a sterile universal container and sent for culture and sensitivity testing. Older reports suggesting an increase in *K. kingae* recovery is gained from inoculating synovial fluid or bony exudates directly into blood-culture bottles have not been replicated in UK practice (16). *K. kingae* is detectable using new PCR techniques from cultures where conventional direct plating of specimens on solid media has been used (17, 18).

Surgical management

There is little current high quality evidence on which to base current surgical practice.

Osteomyelitis

Surgical drainage in acute OM is indicated if the patient is not responding to antibiotics after 48-72hours (although this may be due to resistance) or if there is radiological evidence of a substantial pus collection (6). Best practice is to immobilise any surgically treated limb or focus of infection. Occasionally, where a soft tissue or sub-periosteal collection is clearly demonstrated by ultrasound or MRI, needle aspiration can be performed prior to starting intravenous antibiotics. The procedure should be carried out under sterile conditions. If there is bony destruction or pus aspirated, surgical debridement is usually required. With only early radiographic signs, intravenous antibiotic therapy may suffice.

Historically, the role of surgery is poorly defined. Cole (41) identified three groups of patients: in the group of patients older than one year but who presented within 48 hours, antibiotic therapy alone was sufficient. In a group aged more than one year, five days after the onset of illness, patients usually required surgery and possibly multiple procedures. In infants less than one year in whom the exact diagnosis was difficult to make, a single operation and antibiotic therapy usually sufficed.

In current practice, the relative roles of bacterial virulence and host age and immunity are unclear. More invasive surgery appears more common when bacteria have specific virulence genes, for example PVL (21). While most children recover rapidly with simple medical management, a small proportion may require repeated debridement.

Septic Arthritis

In SA, prompt drainage and washout of the affected joint (either arthroscopic or open) is advocated by some for both diagnostic and therapeutic purposes as the articular cartilage is damaged early (6). The role of surgery in the treatment of septic arthritis is in fact poorly defined except in relation to the hip, where prompt surgical drainage is absolutely necessary. Open capsulotomy to allow continuing drainage of septic material is advocated, and if the arthrotomy does not provide turbid material drilling the femoral neck may decompress a proximal femoral osteomyelitis. The anterior approach is preferred as this also allows open reduction of any displacement of the femoral head.

The indications for surgical drainage of septic joints other than the hip remain controversial. Where there is a large effusion, drainage is usually advocated although in some joints arthroscopic irrigation may be appropriate, such as the knee or ankle. However, with

arthroscopic treatment joint visualisation is less complete. Overall, for joints other than the hip, aspiration, irrigation and IV antibiotic therapy is the preferred first line of treatment. If the patient fails to respond then the joint should be surgically drained, usually by formal open arthrotomy rather than arthroscopic drainage.

Medical Management and Antibiotics

Current evidence for how to initiate treatment:

Intravenous antibiotics are started empirically as soon as the clinical diagnosis of acute OM or SA is made, as delaying therapy until the bacterium is identified increases the risk of complications. In septic arthritis, where urgent surgery is indicated, a widespread pragmatic approach has been to start antibiotics following surgery unless it will take longer than 4 hours to get to theatre. As soon as organisms are isolated, antimicrobial treatment should be adjusted and optimised. In subacute OM with no systemic reaction, oral antibiotics can be used from the start.

Although there has not been a definitive randomised controlled trial, a number of observational and retrospective studies in the literature show several different antibiotic regimes have been effective in treating acute haematogenous osteomyelitis in children, including the use of beta-lactam and macrolide antibiotics (8). The initial antibiotics should always include potent cover against MSSA and GAS, and in younger children against *Kingella kingae*, although the choice will vary according to the age of the child, route of infection and local resistance patterns (7). Activity against *H. influenzae type b* is essential in children who have not been fully immunised against it.

Switch to oral antibiotics and total duration of treatment:

Currently there is no international and little UK consensus regarding the route or duration for antibiotic treatment of acute OAI in children.

a) Oral switch

Sequential intravenous and oral therapy has become usual as it is less inconvenient and painful for the patient, has fewer complications and is cheaper (2, 6, 7). There is no current evidence to aid the clinical decision of when to switch from intravenous to oral therapy, which is widely accepted and usually occurs when the patient has shown a marked clinical improvement (8). A Canadian systematic review of short (≤7 days) versus long course (>7

days) parenteral antibiotic treatment for acute haematogenous OM in children due primarily to Staphylococcus aureus showed no difference in the overall cure rate after 6 months between short course and long course parenteral antibiotic therapy (42). A recent retrospective cohort study of 1969 children in the USA found that early switch to oral therapy (median 4 days) was as effective as prolonged intravenous treatment 43), a finding also suggested in a smaller retrospective study of 186 children with septic arthritis (44). The laboratory or clinical parameters that would determine the decision to switch to oral therapy remain undefined. Most clinicians continue intravenous antibiotics until the child shows clinical improvement, is afebrile and oral fluids and medication could be established.

Additionally, observing a decrease in inflammatory markers such as white blood count (WBC), C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) is thought to be of value (2). Studies have shown that serum CRP level decreased more rapidly than ESR in children recovering from acute osteomyelitis, and that children with a raised CRP level were more likely to have symptoms or extensive radiographic abnormalities(27, 45, 46). A recent Finnish clinical trial showed apparently good long term results and apparently no failure rates using CRP as the biological marker of infection (45, 47). Failure to improve necessitates repeat blood culture, additional imaging for metastatic infection, assessment for deep vein thrombosis, and consideration of unusual pathogens such as PVL *Staphylococcus aureus* or *Fusobacterium*.

No UK consensus currently exists to guide the criteria for oral switch for use in clinical practice or a clinical trial, which will be determined as part of this feasibility study. Currently there is no consensus about the route or duration for antibiotic treatment of acute osteomyelitis in children.

b) Total duration of antibiotic therapy

The suggested duration for parenteral antibiotic treatment ranges from 3 days up to 6 weeks, resulting from several, mainly observational studies with relatively poor level of evidence (8, 48). In the past, the overall duration of antibiotic treatment has been considered an important factor to improve outcome and reduce relapse. Several paediatric textbooks recommend at least 4 to 6 weeks of treatment (2, 49).

Although there are encouraging data from a recent clinical trial in Finland (45, 47) and from other review papers and case series, no recent formal randomized controlled trial has been

conducted to show good evidence for shorter courses of parenteral antibiotic treatment. There are a number of reasons why the recent Finnish data may not be directly applicable to practice in the United Kingdom or other countries in 2011 (50). Some historical observational studies showed an association between short duration of antibiotic therapy and 15-19% poor outcome or relapse with courses of 3 weeks or less (51-53).

c) Oral antibiotic choice and dose

Many different regimens are used as oral therapy following switch from oral antibiotics, including co-amoxiclav, flucloxacillin and clindamycin. Although flucloxacillin and clindamycin have good oral bioavailability and excellent tissue penetration, both drugs have to be given orally 4 times per day and both have poor taste and therefore poor drug adherence of the suspension in small children (54). Although clindamycin rarely leads to *Clostridium difficile* disease in children, there is no current evidence or consensus regarding oral antibiotic choice that will be acceptable to children and parents both in terms of palatability and dose frequency.

d) Continuation of intravenous antibiotics for more than 2 weeks

Complex disease requiring continuing intravenous therapy poses problems of vascular access, hospitalisation and schooling. Most children will require central or peripherally-inserted central venous long line (CVL/PIC) insertion for long term antibiotic treatment. Delivery of subsequent care is either in hospital, or at home dependent on local services and the ability to provide outpatient parenteral antibiotic therapy (OPAT), although OPAT services for children are not yet well developed in the UK. Central venous lines (CVL) or peripherally-inserted central catheters (PICC) and OPAT has attendant risks, with 3-11% CVL associated infection noted in the USA (55, 56).

e) Additional or 2nd line antibiotics for complex disease or where resistant pathogens are identified

Where cases are complex, additional antibiotics may be advised by local microbiologists, clinical infectious diseases specialists or national guidelines, for example PVL positive S. aureus infection (57). Organisms that cause complicated disease may be more readily identifiable using molecular techniques, which may allow antibiotic therapy to be adapted accordingly.

Complications

Deep venous thrombosis and thromboembolism have been seen in up to 30% of children with OM and is associated with a higher risk of disseminated infection (58). In addition, joint stiffness, limb shortening, dislocation (acutely neonates) and avascular necrosis of affected epiphysis may occur. Routine follow-up allows most children with simple disease to be discharged without the need for long-term care or further assessment of growth or function.

In the context of clinical audit or clinical trials, outcome measures may include length of stay in hospital, total length of therapy, operative procedures required as well as formal assessment of growth and function.

3. Aims and objective

We aim to assess the incidence of septic arthritis and osteomyelitis, and the severity and spectrum of disease within the UK. We also aim to assess whether there are significant differences in management between sites, and whether consensus may be gained in future.

This study will inform the future design of a possible randomised controlled trial (RCT) investigating short versus long courses of antibiotic therapy for paediatric bone and joint infections. The results will be used to achieve consensus regarding the antimicrobial agents to be used in different ages within the RCT.

4. Study design

As part of a national service evaluation, we will record demographic details and details of hospitalisation(s) including transfers between hospitals; type and site of disease; routine haematology, biochemistry and microbiology; radiological procedures; surgical procedures; length of IV therapy; antimicrobials used, route and duration; reason/criteria; used for oral switch (if any); and clinical outcomes at 3 months.

This data is to be collected from the patients' clinical notes. Training will be provided for these teams at participating centres. The study will use a password protected web based data collection form that can be accessed at all participating hospitals.

Participant selection

All eligible patients presenting to participating centres with a diagnosis of bone and joint infection will be enrolled with no maximum, and data will be entered into a web-based database. The following eligibility criteria will be applied:

Inclusion criteria

All children from birth to 16 years with a clinical diagnosis of osteomyelitis or septic arthritis admitted to participating hospitals from home, or referred from another centre.

Exclusion criteria

Patients whose parents have specifically requested for their child not to be included in the study.

Participant identification and recruitment

Posters displayed on admitting wards will notify parents and patients that the centre is participating in a national service evaluation of children's bone and joint infections. Parents will have the opportunity to inform a member of their child's care team if they do not want their child's information entered into the database.

Study sponsorship

The sponsor will be University Hospital Southampton NHS Foundation Trust

Data Capture and Confidentiality

Demographic and clinical data will be collected by appropriately trained delegated staff within participating centres and entered into a secure database via a web based system, as part of a national bone and joint infection database involving around 40 participating centres.

Records will be assigned a unique study number and centres will maintain a separate log locally for patient tracking purposes. No data that is identifiable outside of the research team will be kept and the database will be password protected.

Electronic Records

Managed as part of a national service evaluation, the data will be stored and managed by the MCRN Clinical Trials Unit, a division of the UKCRC fully registered Clinical Trials Research Centre based at the University of Liverpool.

Data will be collected using a custom web based data entry system written in c# .Net, using JQuery. These data collection pages will be designed and implemented in the same way as the data collection that was used for the NASH (National Audit of Seizure Management in Hospitals) study - http://www.nashstudy.org.uk/. The NASH study collected data from 130 hospitals, with each hospital entering data for between 20 and 30 participants. The data collection system will allow data to be validated on input, provide help/additional information as required for questions and allow for the hiding of questions that do not need to be answered by the clinician.

Data analysis

Descriptive statistical techniques will be used to analyse the data.

7. Research governance, monitoring and Ethics and R&D approval

The research will comply with the Research Governance Framework and International Conference on Harmonisation Good Clinical Practice (ICH GCP).

The study will be sponsored by University Hospital Southampton NHS Foundation Trust, subject to the relevant governance approvals. The Sponsor will delegate appropriate responsibilities to the Chief Investigator, and to the NIHR Medicines for Children Clinical Trials Unit (study co-applicants) who will co-ordinate the study.

8. Finance

This study is supported by the NIHR HTA project 10/146/01 - Duration of intravenous antibiotic therapy for children with acute osteomyelitis or septic arthritis: a feasibility study

9. Reporting and Dissemination

We will use the normal channels of journal publication and conference presentations. In addition, we are committed to ensuring that our research is available via open access and we will have a dissemination strategy that includes rapid web-based publishing of lay summaries once research articles have undergone peer-review and links to University and Trust press offices.

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THE DINOSAUR STUDY
BONE AND JOINT INFECTION

SERIOUS ADVERSE EVENT REPORTING GUIDANCE

A Serious Adverse Event (SAE) form must be completed and reported to the MCRN CTU as soon as possible if an adverse event occurs in the DINOSAUR study that meets the following criteria:

- meets serious criteria
- is considered to be related to the either the throat swab or additional 5mls of blood taken for the study
- occurs within 2 hours of the throat swab being carried out or within 2 hours of the additional 5mls of blood being taken

Please contact the DINOSAUR trial coordinator should the above occur on Tel: 0151 282 4707.

Serious Criteria:

- results in death
- is life-threatening* (subject at immediate risk of death)
- requires in-patient hospitalisation or prolongation of existing hospitalisation**
- results in persistent or significant disability or incapacity, or
- consists of a congenital anomaly or birth defect
- Other important medical events

*'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
**Hospitalisation is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute an SAE.
***Other important medical events that may not result in death, be life-threatening, or require hospitalisation may be considered a serious adverse event/experience when, based upon appropriate medical judgment, they may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

Relatedness

An event is considered to be 'related' if it is judged to be **possibly, probably** or **almost certainly** related to the throat swab procedure or the taking of the additional 5mls of blood.

1.2 Poster Dinosaur study

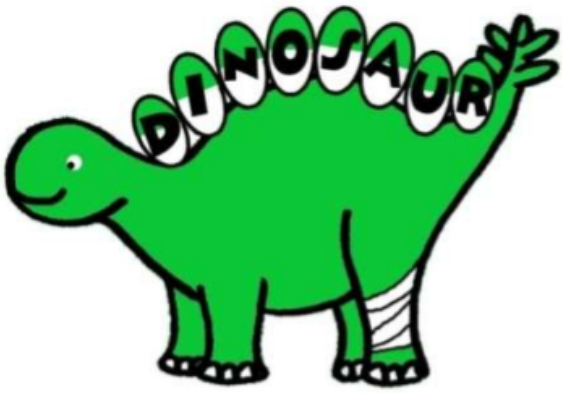
To be presented on local headed paper

Centre Name and Number:

THE DINOSAUR STUDY

(CHILDREN'S BONE AND JOINT INFECTION STUDY)

www.dinosaur-study.org.uk



We are trying to find out the best way to look after children with bone and joint infections by doing a study to look at the bugs causing the infection.

If you are admitted with a bone or joint infection we will be collecting information about your illness to help us treat children with bone and joint infections in the future.

If you do not want us to collect this information, please let your doctor or nurse know.

We would like to ask for the help of children admitted with a bone or joint infection. We will be giving you and your child or teenager an information sheet that explains what we would like to do and why.

If you have any questions, please contact

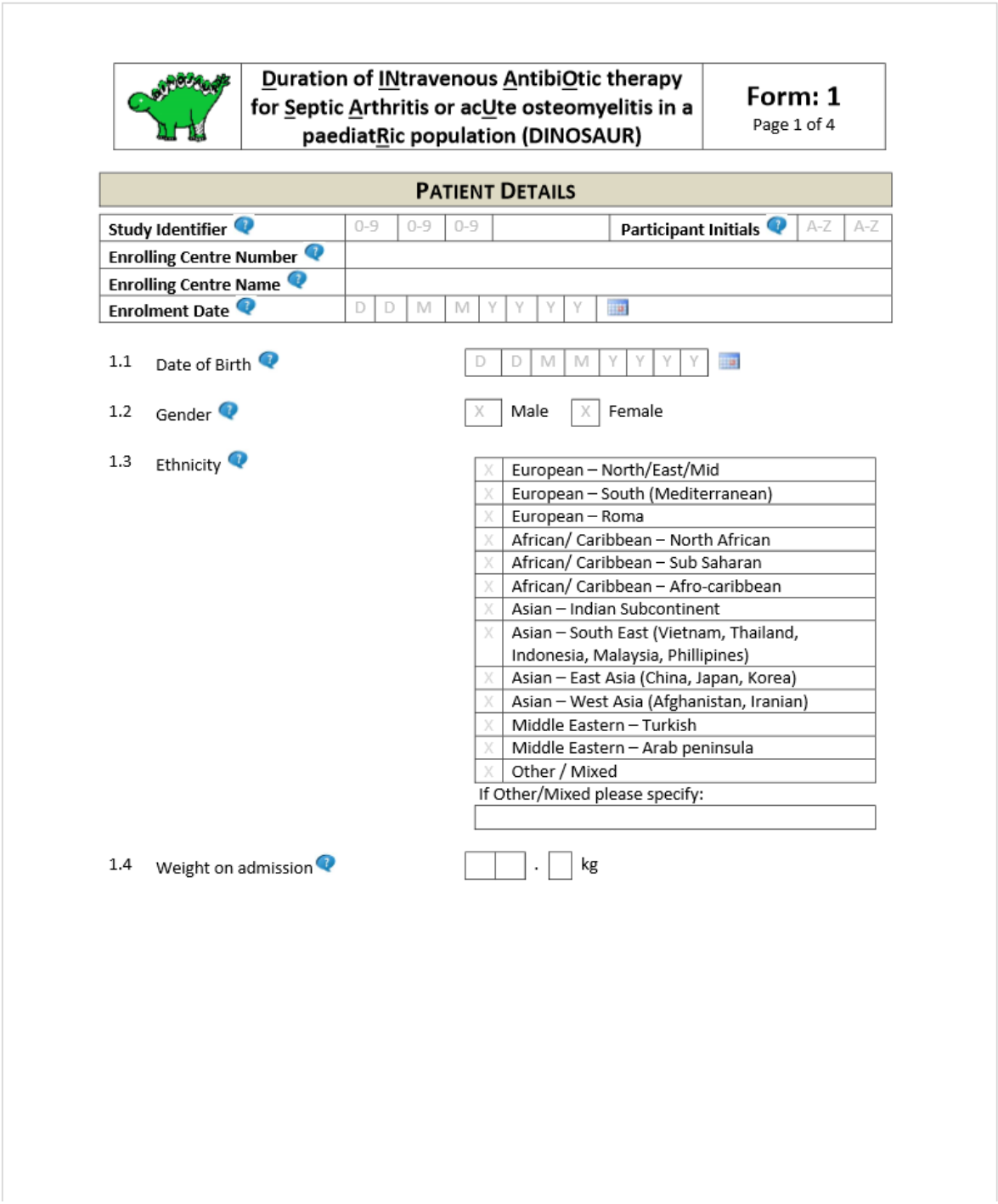
ENTER LOCAL PI/NURSE TELEPHONE

Thank You.

This project was funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (project number 10/146/01) and will be published in full in Health Technology Assessment. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

1.3 Data collection sheet on the website

1.3.1 Form 1: Patient details and previous medical history



	Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form: 1 Page 1 of 4

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		Participant Initials	A-Z	A-Z
Enrolling Centre Number										
Enrolling Centre Name										
Enrolment Date	D	D	M	M	Y	Y	Y	Y		

1.1 Date of Birth — D D M M Y Y Y Y

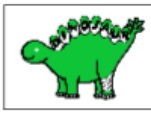
1.2 Gender — [X] Male [X] Female

1.3 Ethnicity

X	European – North/East/Mid
X	European – South (Mediterranean)
X	European – Roma
X	African/ Caribbean – North African
X	African/ Caribbean – Sub Saharan
X	African/ Caribbean – Afro-caribbean
X	Asian – Indian Subcontinent
X	Asian – South East (Vietnam, Thailand, Indonesia, Malaysia, Phillipines)
X	Asian – East Asia (China, Japan, Korea)
X	Asian – West Asia (Afghanistan, Iranian)
X	Middle Eastern – Turkish
X	Middle Eastern – Arab peninsula
X	Other / Mixed

If Other/Mixed please specify:

1.4 Weight on admission — [ ][ ] . [ ] kg

	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form: 1** Page 2 of 4

PREVIOUS MEDICAL HISTORY

1.5 Penicillin allergy — [X] Yes [X] No

1.6 Sickle cell disease — [X] Yes [X] Not Tested [ ]

1.7 Known immunocompromise — [X] Yes [X] No — If yes please complete Q1.9 else go to Q1.10

1.8 Please select one of:

Combined immunodeficiency
HIV
Bone marrow transplant
Chronic granulomatous disease

Specify if other immune deficiency [ ]

transplant date D D M M Y Y Y Y

1.9 Other medical conditions

- [X] Congenital cardiac disease
- [X] Indwelling central venous catheter or PICC ---> [X] less than7 days since insertion; [X] 7 days or more since insertion
- [X] Cystic Fibrosis
- [X] Diabetes Mellitus
- [X] Cerebral Palsy
- [X] Purpura Fulminans — Specify cause if known [ ]
- [X] Malnutrition
- [X] Other — Specify [ ]

1.10	Antibiotics in the last month	☐ Yes	☐ No	If yes please complete Q1.12 else go to Q1.13

1.11 Which antibiotic (select all that apply)

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	Antibiotic	Route		Duration > 1 week	
X	flucloxacillin	X Oral	X IV	X Yes	X No
X	clindamycin	X Oral	X IV	X Yes	X No
X	cefuroxime	X Oral	X IV	X Yes	X No
X	ceftriaxone	X Oral	X IV	X Yes	X No
X	amoxicillin	X Oral	X IV	X Yes	X No
X	co-amoxiclav	X Oral	X IV	X Yes	X No
X	rifampicin	X Oral	X IV	X Yes	X No
X	vancomycin	X Oral	X IV	X Yes	X No
X	fusidic acid	X Oral	X IV	X Yes	X No
X	benzyl penicillin	X Oral	X IV	X Yes	X No
X	teicoplanin	X Oral	X IV	X Yes	X No
X	other				

If Other

Name	Route		Duration > 1 week	
	X Oral	X IV	X Yes	X No
	X Oral	X IV	X Yes	X No
	X Oral	X IV	X Yes	X No

1.12 Immune modulating treatment in last 6 months X Yes X No

Which treatment?

Steroid 2mg/kg for >=1 week or 1mg/kg for >=1 month

- X Radiotherapy
- X Chemotherapy
- X Azathioprine
- X Cyclosporin
- X Cyclophosphamide
- X Rituximab
- X Lefluvomide
- X Tacrolimus
- X Sirolimus
- X Other Please specify

1.13 Infection History in the last 12 months

[X] None

- [X] Pneumonia
- [X] Septicaemia
- [X] Pyelonephritis
- [X] Cellulitis / soft tissue infection
- [X] Meningitis
- [X] Osteoarticular infection
- [X] Abdominal sepsis
- [X] Other

1.14 History of trauma in the last month [X] Yes [X] No

Date	Area affected	R/L	History	Surgery
D D M M Y Y Y Y	[X] Head [X] Neck [X] Forearm [X] Arm [X] Abdomen [X] Back [X] Buttock [X] Thigh [X] Knee [X] Lower leg [X] Ankle [X] Foot	R L	[X] Laceration [X] Sprain [X] Fracture [X] Open fracture [X] Haematoma	Y N

1.15 History of orthopaedic surgery [X] Yes [X] No

Date	Bone	R/L	Procedure Details
D D M M Y Y Y Y	[X] Radius [X] Ulna [X] Humerus	R L	

1.16 History of other surgery [X] Yes [X] No

Date	Details
D D M M Y Y Y Y	

1.3.2 Form 2: Current OAI

Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR) | **Form: 2** Page 1 of 2

CURRENT OAI

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z		
Enrolling Centre Number									
Enrolling Centre Name									

2.1. Date of first symptoms D D M M Y Y Y Y

2.2. Date of first presentation D D M M Y Y Y Y

to
- GP [X]
- Emergency Department [X]
- Walk-In Centre [X]
- N/A [X]

2.3. Hospital Admission

Date	Hospital	Diagnosis	Reason for transfer
D D M M Y Y Y Y		Osteomyelitis [X] Septic arthritis [X] Septicaemia [X] Cellulitis [X] Other [X] specify	Surgical [X] Management Medical [X] Other [X] specify No transfer

2.4. Date of discharge from hospital (to home) D D M M Y Y Y Y

2.5. Date treatment completed D D M M Y Y Y Y

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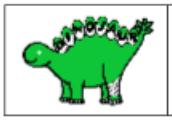
Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR) | **Form: 2** Page 2 of 2

2.6. Bones or joints affected
a) Hip
b) Shoulder
c) Knee
d) Ankle
e) Wrist
f) Skull
g) Mandible
h) Humerus
i) Clavicle
j) Radius
k) Ulna
l) Pelvis
m) Rib
n) Femur
o) Sternum
p) Elbow
q) Foot
r) Calcaneum
s) Tibia
t) Fibula
u) Lumbar vertebra
v) Thoracic vertebra
w) Sacrum
x) Cervical vertebra

Infected implant: Yes / No

Version 1.6 (23/01/2013)

1.3.3 Form 3: Surgical procedures



Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form: 3 Page 1 of 2

SURGICAL PROCEDURES

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z
Enrolling Centre Number							
Enrolling Centre Name							

3.1 Surgical Procedures Undertaken [X] Yes [X] No

If "Yes" please complete this form for all surgical procedures undertaken for this participant.

	Hospital	Date	Time of Procedure	Description

Add New

Note:

(1) The table displayed on this page will provide a summary of the data entered for this participant
(2) Clicking on the associated with a record will allow editing of that record.
(3) Clicking on the "Add New" button will allow a new record to be entered.
(4) Actions (2) and (3) will result in the form on the following page being displayed to the user.

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SURGICAL PROCEDURES

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z
Enrolling Centre Number							
Enrolling Centre Name							

Hospital	
Date of Procedure	D D M M Y Y Y Y
Time of procedure	h h : m m
Description	X Aspiration X Incision and drainage X Drill decompression X Curettage/excision X Arthrotomy X Arthroscopy X Amputation X Debridement X Fasciotomy X Compartment decompression X Secondary closure X Skin graft X Other plastic surgery If "other plastic surgery" please specify:
Additional Notes	

1.3.4 Form 4: Immobilisation

	Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form: 4 Page 1 of 1

IMMOBILISATION

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	Participant Initials	A-Z	A-Z
Enrolling Centre Number							
Enrolling Centre Name							

4.1 Participant Immobilised since diagnosis [X] Yes [X] No

Version 1.6 (23/01/2013)

1.3.5 Form 5: Antibiotics

	Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form: 5 Page 1 of 1

ANTIBIOTICS

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z	
Enrolling Centre Number								
Enrolling Centre Name								

5.1 Antibiotics prescribed [X] Yes [X] No

Antibiotic	Hospital (Centre#)	mg/dose	Frequency	Route	Date Started (dd/mm/yyyy)	Date Stopped (dd/mm/yyyy)	Ongoing	Reason stopped
flucloxacillin [X] clindamycin [X] cefuroxime [X] Ceftriaxone [X] amoxicillin [X] co-amoxiclav [X] rifampicin [X] vancomycin [X] fusidic acid [X] benzyl penicillin [X] teicoplanin [X] Other [X] Specify: _____	[Autopopulated from data entry person]			IV [X] Oral [X] IM [X] SC [X]	DD/MM/YYYY	DD/MM/YYYY	[X]	

Version 1.6 (23/01/2013)

1.3.6 Form 6: Microbiology

Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form: 6 Page 1 of 1

MICROBIOLOGY SAMPLES

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z
Enrolling Centre Number							
Enrolling Centre Name							

5.1 Antibiotics prescribed [X] Yes [X] No

Antibiotic	Hospital (Centre#)	Date Started (dd/mm/yyyy)	mg/dose	Frequency	Route	Date Stopped (dd/mm/yyyy)	Ongoing	Reason stopped
flucloxacillin [X] clindamycin [X] cefuroxime [X] Ceftriaxone [X] amoxicillin [X] co-amoxiclav [X] rifampicin [X] vancomycin [X] fusidic acid [X] benzyl penicillin [X] teicoplanin [X] Other [X] Specify: _____	[Autopopulated from data entry person]	DD/MM/YYYY			IV [X] Oral [X] IM [X] SC [X]	DD/MM/YYYY	[X]	

Version 1.6 (23/01/2013)

1.3.7 Form 7: Bloods

	Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form: 7 Page 1 of 1

BLOOD RESULTS

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z	
Enrolling Centre Number								
Enrolling Centre Name								

5.1 Blood sample taken? [X] Yes [X] No

Hospital (Centre#)	Date (dd/mm/yyyy)	Hb	WCC	Neutrophils	Platelets	CRP	ESR
[Autopopulated from data entry person]	DD/MM/YYYY						

Version 1.6 (23/01/2013)

1.3.8 Form 8: Imaging

1.3.9 Guideline for radiologists reporting images

Guideline for Radiologists Reporting Images for DINOSAUR Study

Dear Radiology team,

Thank you very much for your support with this study; it is greatly appreciated by the research team.

The DINOSAUR study is an NIHR HTA funded, multicentre service evaluation, looking at all children presenting to participating hospitals with osteoarticular infections. Currently there is little international or UK consensus regarding the route or duration of antibiotic treatment for acute osteomyelitis (OM)/septic arthritis (SA) in children. Data regarding paediatric bone and joint infections in the UK are scarce and outdated.

The aims of this study are to

1. Assess current case load, disease spectrum & clinical practice in the diagnosis & treatment of OM/SA in secondary & tertiary UK care

2. Determine whether a randomised controlled trial to investigate shorter duration of intravenous antibiotic therapy for bone and joint infections in children is feasible in the future.

3. This will be achieved in conjunction with a future component of the study obtaining qualitative & quantitative data on:

    a) willingness of clinicians to randomise to proposed protocol
    b) willingness of patients & parents to be randomized
    c) clinical stakeholder & consumer perception of relevant outcomes

The imaging and radiological diagnosis are an important part of this service evaluation.

Information is being collected using a web based data collection form will usually be completed by a research nurse, using the radiology report. Please find enclosed the data collection form for imaging. It would be helpful if the report could be written to allow all of these sections to be filled in by the research nurse.

Thank you very much for your help and understanding. Please contact the research team if you have any queries or comments regarding the study:

Dr Priya Sukhtankar

Clinical Research Fellow, University Hospital Southampton

p.sukhtankar@soton.ac.uk

02380 794956

1.3.9.1 - Form for X-ray report

Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form 8a X-Ray Report

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		Participant Initials	A-Z	A-Z
Enrolling Centre Name							

SUMMARY OF X-RAY RESULT

Number of views ☐

Date of X-Ray D D M M Y Y Y Y

X-Ray result: Normal ☐ Abnormal ☐ *Please complete below*

Abnormalities:

	Yes	No
a) Soft tissue swelling?	☐	☐
b) Focal bone lytic change?	☐	☐
i) Focal	☐	
ii) Diffuse	☐	
c) Periosteal reaction	☐	☐
d) Cortical loss or destruction	☐	☐
e) Physeal widening	☐	☐
f) Fracture	☐	☐
g) Bony sequestrum	☐	☐

h) Epiphysis Normal ☐ Abnormal ☐

	Yes	No
i. Lucency	☐	☐
ii. Sclerosis	☐	☐
iii. Epiphyseal separation	☐	☐

i) Radiological diagnosis *(select one option)*

i. Probable acute OM ☐
ii. Probable sub-acute OM ☐
iii. Chronic OM ☐

1.3.9.2 - Form for CT scan report

Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form 8b CT Report

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		Participant Initials	A-Z	A-Z
Enrolling Centre Name							

SUMMARY OF CT SCAN

Date of CT D D M M Y Y Y Y

CT result: Normal ☐ Abnormal ☐ *Please complete below*

Abnormalities:

	Yes	No
a) Soft tissue swelling?	☐	☐
b) Focal bone lytic change?	☐	☐
i) Focal	☐	
ii) Diffuse	☐	
c) Periosteal reaction	☐	☐
d) Cortical loss or destruction	☐	☐
e) Physeal widening	☐	☐
f) Fracture	☐	☐
g) Bony sequestrum	☐	☐

h) Epiphysis Normal ☐ Abnormal ☐

	Yes	No
i. Lucency	☐	☐
ii. Sclerosis	☐	☐
iii. Epiphyseal separation	☐	☐

i) Radiological diagnosis *(select one option)*

i. Probable acute OM ☐
ii. Probable sub-acute OM ☐
iii. Chronic OM ☐

1.3.9.3 - Form for Ultrasound scan report

	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form 8c Ultrasound**

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		**Participant Initials**	A-Z	A-Z
Enrolling Centre Name							

SUMMARY OF ULTRASOUND RESULT

Date of Ultrasound D D M M Y Y Y Y

Ultrasound Result: Normal ☐ Abnormal ☐ *Please complete below*

Abnormalities:

	Yes	No
a) Periosteal reaction	☐	☐
b) Cortical breach/destruction	☐	☐
c) Sub-periosteal collection/abscess	☐	☐
d) Muscle increased echogenicity	☐	☐
e) Focal muscle/soft tissue abscess/abscesses	☐	☐
f) Joint effusion?	☐	☐
Echogenic?	Yes ☐	No ☐

1.3.9.4 - Form for MRI scan report

Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form 8d MRI Report

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		**Participant Initials**	A-Z	A-Z
Enrolling Centre Name							

SUMMARY OF MRI RESULT

Date of MRI D D M M Y Y Y Y

Technique:

Gadolinium enhancement — With ☐ Without ☐
*If Gadolinium enhancement not used, **go to Section 2***

Fat suppression — With ☐ Without ☐

Diffusion — Diffusion ☐ No Diffusion ☐

MRI result: Normal ☐ Abnormal ☐ *Please complete findings below*

Section 1

	Yes	No	Not applicable
a. Focal marrow enhancement after gadolinium	☐	☐	☐
b. Muscle enhancement after gadolinium (myositis)	☐	☐	☐
c. Focal abscess (defined as ring enhancement after gadolinium on T1 high signal on STIR/ T2FS)	☐	☐	☐
i. Intra-osseous (bone marrow) abscess	☐	☐	
ii. Sub-periosteal abscess	☐	☐	
iii. Soft tissue abscess - *select from options below*	☐	☐	
1) Deep parosteal	☐	☐	
2) Muscle	☐	☐	
3) Soft tissues/ fascial plains	☐	☐	

	Yes	No	Uncertain
d. Physeal involvement - enhancement of the physis after gadolinium	☐	☐	☐

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	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form 8d MRI Report**

Section 2		Yes	No	Uncertain
	a. Abnormal marrow signal	☐	☐	
	i. Low signal on T1	☐	☐	
	ii. High on STIR/ T2FS	☐	☐	
	b. Abnormal muscle signal on T1 (low) and STIR/T2FS (High)	☐	☐	
	c. Joint involvement (septic arthritis)	☐	☐	
	i. Joint effusion	☐	☐	
	ii. Synovial enhancement	☐	☐	
		Yes	No	Uncertain
	d. Physeal involvement – Increased signal intensity or widening of the physis on STIR/T2FS	☐	☐	☐

1.3.9.5 - Form for bone scan report

	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form 8e Bone Scan**

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		**Participant Initials**	A-Z	A-Z
Enrolling Centre Name							

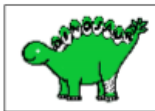
SUMMARY OF NUCLEAR MEDICINE (TECHNETIUM BONE SCAN) RESULT

Date of Bone Scan D D M M Y Y Y Y

Bone Scan Result: Normal ☐ Abnormal ☐ *Please complete below*

Abnormalities:		Yes	No
	i) Solitary lesion with increased uptake	☐	☐
	ii) Multiple lesions with increased uptake	☐	☐

1.3.10 Form 9: Complications

	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form: 9** Page 1

COMPLICATIONS

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z
Enrolling Centre Number							
Enrolling Centre Name							

4 Any Complications [X] Yes [X] No

If Yes please give details

.....

.....

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SURGICAL PROCEDURES

Study Identifier	0-9	0-9	0-9	(Auto Assigned)	**Participant Initials**	A-Z	A-Z		
Enrolling Centre Number									
Enrolling Centre Name									

Hospital	
Date of Procedure	D D M M Y Y Y Y
Time of procedure	h h : m m
Description	X Aspiration X Incision and drainage X Drill decompression X Curettage/excision X Arthrotomy X Arthroscopy X Amputation X Debridement X Fasciotomy X Compartment decompression X Secondary closure X Skin graft X Other plastic surgery If "other plastic surgery" please specify:
Additional Notes	

1.3.11 Form 2a: Discharge form

Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form 2A Discharge form

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		Participant Initials	A-Z	A-Z
Enrolling Centre Name							

DISCHARGE SUMMARY

Date of discharge: D D M M Y Y Y Y

	Yes	No
1) PIC line in situ at discharge?	☐	☐
2) Peripheral cannula in situ at discharge?	☐	☐

3) Planned Antibiotic therapy at discharge:

Antibiotic Name (if other please specify)	*Daily dose (mg)*	*Route*	*Planned duration (days)*
		IV ☐ *Oral* ☐	
		IV ☐ *Oral* ☐	
		IV ☐ *Oral* ☐	
		IV ☐ *Oral* ☐	
		IV ☐ *Oral* ☐	
		IV ☐ *Oral* ☐	

1 Flucloxacillin 2 Clindamycin 3 Cefuroxime 4 Ceftriaxone 5 Amoxicillin 6 Co-amoxiclav 7 Rifampicin 8 Vamcomycin 9 Fusidic Acid 10 Benzyl penicillin 11 Teicoplanin 12 Fluconasole	13 Amphotericin b 14 Itraconazole 15 Caspofungin 16 Micafungin 17 Anidulafungin 88 Other antibiotic 89 Other antifungal	

	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form 2A** **Discharge form**

4) Follow-up planned	Yes	No	
Discharged from follow-up	☐	☐	
X rays	☐	☐	
MRI	☐	☐	
Growth monitoring	☐	☐	
Physiotherapy	☐	☐	
Orthotic e.g. brace	☐	☐	
General paediatric follow-up	☐	☐	
Orthopaedic follow-up	☐	☐	
Removal of line	☐	☐	
Other follow up (please specify if yes)	☐	☐	

1.3.12 Form 10: Three month follow up

	Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)	Form 10 3 Month Follow-up

PATIENT DETAILS

Study Identifier	0-9	0-9	0-9		**Participant Initials**	A-Z	A-Z
Enrolling Centre Name							

DETAILS OF 3 MONTH FOLLOW-UP

Date of follow-up D D M M Y Y Y Y

Please tick here if unable to contact patient or patient did not attend ☐

Type of follow-up

Orthopaedic OP Appointment ☐

Paediatric OP Appointment ☐

Telephone call ☐

1) Readmission to hospital related to current SA/OM diagnosis? Yes ☐ No ☐

Reason for readmission 1:

Date of readmission 1: D D M M Y Y Y Y — *Approx date* ☐ *Actual date* ☐

Reason for readmission 2:

Date of readmission 2: D D M M Y Y Y Y — *Approx date* ☐ *Actual date* ☐

Reason for readmission 3:

Date of readmission 3: D D M M Y Y Y Y — *Approx date* ☐ *Actual date* ☐

Please complete/update microbiology form if applicable (hyperlink)

2) Ongoing symptoms

	Yes	No		Yes	No
Pain	☐	☐	Fracture	☐	☐
Fever >38C	☐	☐	Sinus	☐	☐
Joint stiffness	☐	☐	Deformity	☐	☐
Immobility	☐	☐			

	Duration of **IN**travenous **A**ntibi**O**tic therapy for **S**eptic **A**rthritis or ac**U**te osteomyelitis in a paediat**R**ic population (DINOSAUR)	**Form 10** **3 Month Follow-up**

FOLLOW-UP OF LINES INSERTED

Please tick here if this section is not applicable to the participant *(no line in situ at time of discharge and no lines inserted after discharge).* ☐

	Type of line		Date line inserted		Current status of line	Date of removal (if applicable)		Line infection? *
1	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No
2	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No
3	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No
4	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No
5	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No
6	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No
7	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No
8	☐ PIC Line ☐ Other intravenous catheter	☐ If other line, specify:	__/__/__	☐ Approx date ☐ Actual date	☐ In situ ☐ Removed	__/__/__	☐ Approx date ☐ Actual date	☐ Yes ☐ No

* any time between discharge and this follow-up

Please update microbiology form

	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form 10** **3 Month Follow-up**

ANTIBIOTIC THERAPY

3) Course of antibiotic therapy completed as planned? (based on antibiotic regimen at discharge).

Yes ☐ No ☐ *Please update Form 5 with end date for these antibiotics where possible. (hyperlink)*

→ **Reason antibiotics stopped early**

	Yes	No	
Unpalatable antibiotic	☐	☐	
Diarrhoea	☐	☐	
Rash	☐	☐	
Resolution of symptoms	☐	☐	
Other	☐	☐	*Specify:*

Decision to stop antibiotics:

	Yes	No	
Parent decision	☐	☐	
Hospital decision	☐	☐	*Details:*
GP medical decision	☐	☐	

CHANGES TO PLANNED ANTIBIOTIC THERAPY *(AS PER PLAN AT DISCHARGE)*

4) Were oral antibiotics changed? Yes ☐ No ☐ →

Changed by:	Yes	No
GP	☐	☐
Hospital	☐	☐

Reason for change

	Yes	No	
Unpalatable antibiotic	☐	☐	
Diarrhoea	☐	☐	
Rash	☐	☐	
Recurrence of infection	☐	☐	
Other (e.g. resistant organism)	☐	☐	*Details:*

	**Duration of INtravenous AntibiOtic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population (DINOSAUR)**	**Form 10** **3 Month Follow-up**

DETAILS OF FOLLOW-UP

5) Follow-up planned

	Yes	No	
X rays	☐	☐	
MRI	☐	☐	
Growth monitoring	☐	☐	
Physiotherapy	☐	☐	
Orthotic e.g. brace	☐	☐	
General paediatric follow-up	☐	☐	
Orthopaedic follow-up	☐	☐	
Discharged from follow-up	☐	☐	
Other follow-up (please specify if yes)	☐	☐	

6) Please select any follow-ups that have already taken place:

	Yes	No	Outcome		
X rays	☐	☐	Normal ☐ Abnormal ☐	*Details if abnormal:*	
MRI	☐	☐	Normal ☐ Abnormal ☐	*Details if abnormal:*	
Physiotherapy	☐	☐	*Details:*		
Orthotic e.g. brace	☐	☐			
General paediatric follow-up	☐	☐			
Orthopaedic follow up	☐	☐			