# Qualitative Study documents

## 1.1 Protocol Qualitative study

Duration of Intravenous antibiotic therapy for Septic Arthritis or acUte osteomyelitis in a paediatRic population: QUALITATIVE SUB-STUDY

Sponsor: University Hospital Southampton NHS Foundation Trust

Sponsor Code: RHM CHI 0725

NHS REC No: 14/YH/1166

Protocol Version: 1.0 date 11 June 2014

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NIHR Wellcome Trust Clinical Research Facility

University Hospital Southampton

Qualitative study to explore the views of parents and paediatric patients, who have had bone and/or joint infection about participating in a hypothetical randomised controlled investigating shortened duration of intravenous antibiotic therapy for osteomyelitis and septic arthritis

## 1. INTRODUCTION AND BACKGROUND

Osteomyelitis (OM) and septic arthritis (SA) are relatively unusual infections in children, however, they confer considerable morbidity. At present there is limited evidence and no UK or global consensus on how to optimally treat these infections with antibiotics. The DINOSAUR study (Duration of Intravenous Antibiotic Therapy for Acute Osteomyelitis and Septic Arthritis in a Paediatric Population) has 3 components to determine the feasibility of whether a trial of shortened courses of intravenous and oral antibiotics for the treatment of bone and joint infections in children will be feasible in the UK. (www.dinosaur-study.org.uk). The feasibility study comprises a service evaluation, Delphi survey and stakeholder meeting to establish consensus from the different clinical stakeholder groups, and a qualitative study to input young people and parent's views into the Delphi and stakeholder process.

Parents were consulted during the proposal application for the DINOSAUR study and agreed that a qualitative component engaging parents of children who had had bone and joint infections would be beneficial. This qualitative study incorporates parents' views and experiences into in the question of whether a formal clinical trial will be feasible.

Historically patients with OM/SA have been treated with up to six weeks intravenous antibiotics as inpatients in hospital. It is now more common practice to treat paediatric OM/SA with intravenous antibiotics initially, and then switch to oral antibiotics once clinical improvement is seen, and the child is able to take and absorb oral antibiotics. An alternative has been the use of outpatient intravenous antibiotic therapy (OPAT) before the switch to oral medicines. The criteria for switching from intravenous to oral antibiotics, and the total duration of antibiotics varies between centres within the UK and internationally.

Diagnosis of OM/SA combines haematological and biochemical blood results, microbiological analysis of blood and tissue samples and imaging using plain x-rays, ultrasound and MRI scan. Treatment may include surgery, such as drainage of a joint, and drilling and decompression, although the mainstay of treatment is immediate, intravenous antibiotic therapy.

The advantages of switching from intravenous to oral antibiotics are that the duration of hospital stay may be shortened. Additionally the risks of line-site infection and bacteraemia when a venous catheter is in place for antibiotic administration for prolonged periods are

reduced. Where used, these intravenous lines may need replacing if they become occluded or displaced necessitating hospital admission and often general anaesthetic for the procedure.

The advantage of prolonged intravenous therapy is guaranteed delivery of the antibiotic, not dependent on child or family-specific factors such as adherence or absorption. This allows more reliable treatment of invasive and potentially destructive infection.

Prolonged intravenous therapy may increase the risks of reaction to the antibiotic, and side effects such as bone marrow suppression. On the other hand, incompletely or inadequately treated bone or joint infection may rarely lead to chronic infection with destruction of cartilage, bone and growth plate, which can then cause permanent deformity and disability. However, whilst it may be desirable for many families to spend less time in hospital, with reduced duration of intravenous therapy, the perception of risks of complications secondary to potentially incomplete treatment may mean that a trial of shortened duration of antibiotics is not acceptable to parents and/or clinical stakeholders.

There has been little previous qualitative research exploring the views of paediatric patients or their parents about treatment for or the impact of acute bone and joint infections, or of the medical or surgical treatment family life during and after admission to hospital with infection in a previously healthy child. Additionally, evidence regarding patient and parent perception and understanding of risks of complications, disability or adverse effects of treatment remains anecdotal.

Importantly, the willingness of parents and patients to participate in a RCT, and what factors may influence this is not known, and will vary depending on proposed study design.

The importance of patient and family involvement (PPI) in NHS based research has become a priority at all stages of development of research projects. This qualitative study will involve patients and parents in assessing the feasibility of a future RCT, by determining their willingness to participate in a trial once specific potential study outcomes have been considered. Parents and patients may prioritise outcomes of a randomised controlled trial differently from clinicians, and this qualitative study will identify which outcomes are most important to parents and children, and where possible these can be incorporated as important outcomes to assess in a RCT.

**DINOSAUR Qualitative Sub-study Team**

Professor Saul Faust is the Chief Investigator of the DINOSAUR study as a whole and will oversee this study.

Dr Claire Ballinger is an experienced qualitative researcher and patient-public involvement lead, who will lead the qualitative methodology and supervise the qualitative researcher employed to interview young people and families.

Dr Amanda Lees, a trained qualitative researcher, who has previous experience interviewing families including children will be employed for six months to conduct the interviews and analyse the transcripts, supervised by Dr Ballinger. She may be assisted by another trained and experienced qualitative researcher.

Dr Priya Sukhtankar is the clinical research fellow based at the Southampton NIHR Wellcome Trust Clinical Research Facility coordinating clinical aspects of the DINOSAUR trial and liaising with individual sites.

Other investigators:

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## 2. AIMS OF STUDY

Qualitative research aims to understand: how social (including health) experiences are understood; uses methods which are sensitive to social context; and employs analytic strategies which involve an appreciation of complexity and context [1]. The research methodology employed within this study will draw on constructivist grounded theory [2]. This study aims to explore parents' and children's views, understanding and experiences of both bone and joint infections and treatment, and the parental willingness to participate in a future clinical trial.

Detailed aims:

1. To explore the experiences of parents and children treated with intravenous and/or oral antibiotic therapy for bone and joint infection about their condition and understanding about treatment

2. To identify which clinical outcomes are most important to parents and young people with bone and joint infections, in order to contribute to the wider clinical stakeholder Delphi and stakeholder consultation process.

3. To explore the views of parents and children admitted to hospital with bone and joint infections about participating in a RCT, in particular focusing on: information required in order to provide informed consent; views about and acceptability of potential interventions;

willingness to be randomised to either arm (i.e. treatment or control); influences on these factors.

## 3. METHODS

*Semi-structured interviews*

Semi-structured interviews will be used within this study to explore the views and experiences of parents and children who have had bone and joint infections. Parents and children will be interviewed together. Semi-structured interviews are characterised by:

- an interactional exchange
- a topic centred dialogue, but with a flexible structure
- an acknowledgement that within an interview context, meaning and knowledge is co-produced [1]

The interview guides for parents and children will be developed with reference to existing literature (e.g. qualitative work in this field, factors impacting on participation in RCTs, qualitative research interviews with children); by experts in the field including our Research Fellow, Dr Amanda Lees, and in consultation with our patient and public involvement contributors. The interview guide will be piloted with between three and five children and their parents, (although as is usual practice in qualitative research, these data will be included in the final analysis).

The interviews will be digitally recorded, with permission from the families and children, all identifying features will be omitted, and the recordings will then be transcribed by a professional transcribing agency. The transcriptions will then be returned to the qualitative researcher for analysis.

*Sample and Consent*

A purposive sample of children aged 0 to 16 years who have had bone and joint infection within the previous year will be identified from seven centres who have participated in the main Dinosaur service evaluation. The purposive sample strategy will be developed to address variation with regard to age, gender, and ethnicity. Parents/carers, and, where appropriate and consent has been obtained, young people, will be interviewed together with their parents. We anticipate that a sample size of thirty families should be sufficient, but will

continue sampling until data saturation is reached. [3] All families approached who agree to participate will be interviewed.

*Inclusion criteria*

- Parents and children from 3months to sixteen-years-old with osteomyelitis and septic arthritis
- who have been treated for bone and joint infections at seven sites identified below
- who have consented to take part in this qualitative study

Children and their parents at the following seven sites have participated in the main DINOSAUR study: Bristol Children's Hospital, Oxford Children's Hospital (University Hospitals Oxford NHS Trust), University Hospital Southampton NHS Foundation Trust, Imperial College Healthcare (St Mary's Hospital London), St George's Hospital London, Birmingham Children's Hospital and Liverpool Alder Hey Hospital. At the point of initial consent for participation in the larger study, participants (i.e. children and their families) were also asked if they would be willing to be contacted about possible participation in a smaller qualitative study. Once ethics and site specific approvals have been received, letters will be sent to those parents and children consenting to be contacted about the qualitative study, to include Participant Information Sheets. Potential participants will be invited to make contact with the research team if they are interested in hearing more. The qualitative researcher will make contact with interested parents and children to explain further about the study, answer any queries, and arrange to meet.

On meeting, any additional concerns/queries will be addressed, and if happy to continue, written consent will be received immediately prior to conduct of the interview.

## 4. TIME LINE

We anticipate contacting families early October 2014, with a view to organising interviews between October 2014 and January 2015.

## 5. DATA ANALYSES

As is usual in qualitative analysis, data collection and analysis will occur concurrently, in this instance using the constant comparative method. Analysis will move from the generation of initial 'in vivo' codes to more abstract, theoretical frameworks, which explain the vast majority of the data generated [2]. The qualitative research will also use memos to capture

analytic thoughts and ideas which will inform the analysis, and will also provide evidence of an audit trail, one of the strategies which can demonstrate the credibility of the analysis [4]

## 6. RESEARCH GOVERNANCE, MONITORING, 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 Dr Ballinger (lead qualitative researcher) who will co-ordinate the study and will during pilot phase provide at least weekly supervision, and thereafter a minimum of two weekly supervision to Dr Amanda Lees.

There are some ethical considerations with this study that requires trained researchers not directly involved with the patients' medical care to have access to limited confidential information.

## 7. 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

## 8. 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.

## 9. REFERENCES

1. Mason, J, Qualitative Research, Qualitative Researching, Second Edition, SAGE Publications 2002

2. Charmaz, K.C. Constructing Grounded Theory, SAGE Publications 2006

3. Baker, S.E. and Edwards R, How Many Qualitative Interviews is Enough? http://eprints.ncrm.ac.uk/2273/ National Centre for Research Methods Review Paper

4. Ballinger, C 'Writing up rigour: Representing and evaluating good scholarship in qualitative research' British Journal of Occupational Therapy 67 (12) 540-7. (2004)

## 1.2 RCT process diagram and information

Possible trial design

In the past, patients with bone and joint infections stayed in hospital for up to 6 weeks, and were treated with intravenous antibiotics. This is what we could call the 'text book' treatment.

Nowadays, it is more common for patients to be given intravenous antibiotics at first, with a switch being made to oral antibiotics (tablets or medicine), when they start to get better. There has also been a move towards using less total antibiotic treatment, but the exact length of treatment varies within the UK and similar countries abroad.

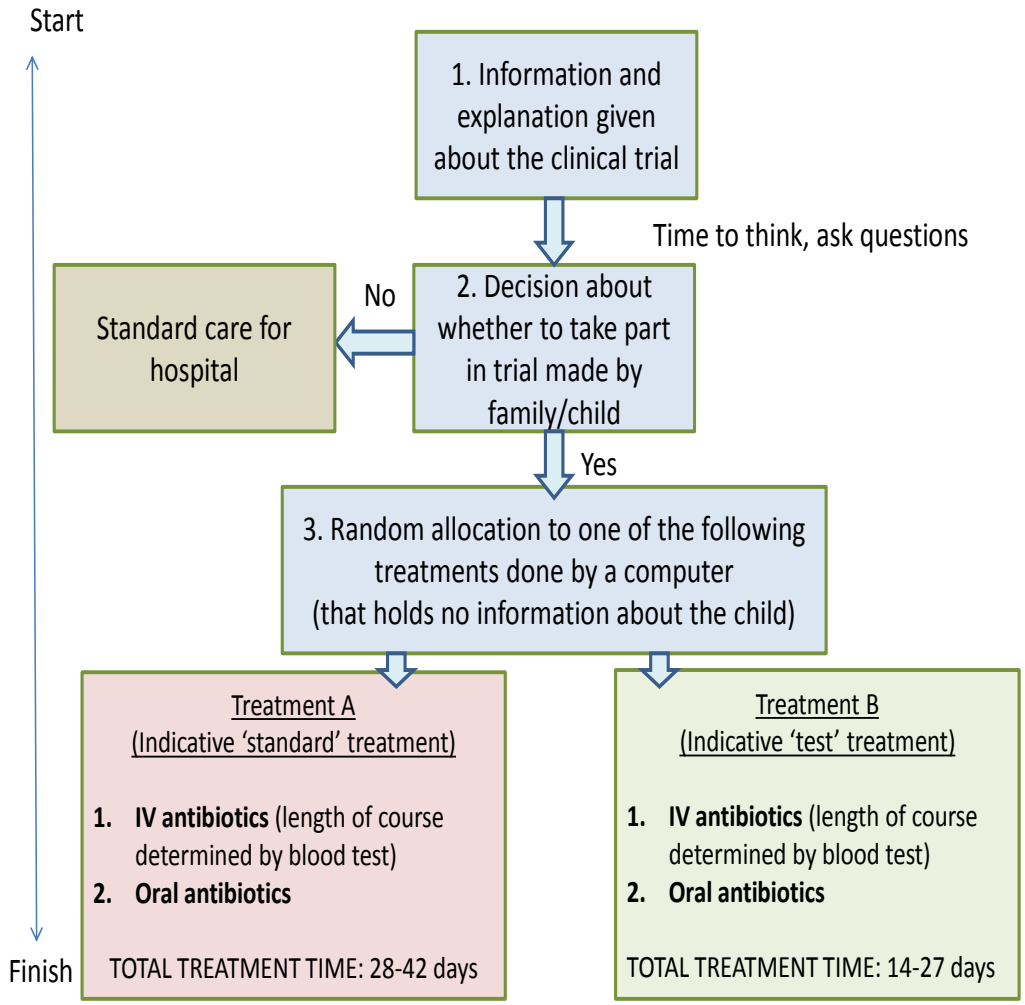
At the moment, doctors do not have clear evidence about the best length of time for patients to stay on intravenous antibiotics, or on the signs of improvement that show a switch to oral antibiotics can be made.

Conducting a clinical trial would determine:

- The best length of the total antibiotic treatment and whether this could be shortened
- The best length of intravenous antibiotic treatment, and the signs of recovery needed before a switch to oral antibiotics can be made
- The best length of oral antibiotic treatment

The process for the trial is shown on the next page. This type of trial is called a randomised controlled trial. It compares two groups of people: one group who receive the new treatment and another group, who receive the standard treatment (this group is called the 'control group'). The control group allows the researchers to see whether the treatment they are testing is any more or less effective than the usual or standard treatment. In a randomized controlled trial, the decision about which group a person joins is random (i.e. based on chance). A computer will decide rather than the researcher or the participant. Randomization ensures that the two groups are as similar as possible, except for the treatment they receive. This is important because it means that the researcher can be sure that any differences between the groups are only due to the treatment.

**FIGURE 1: PROCESS FOR PROPOSED TRIAL**



# Some questions

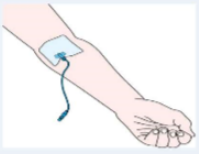
- Who/where should study information come from?
- What information would you like?
- How long would you need to think/decide?
- Who would you talk to?
- How would you feel about being randomly allocated to a treatment arm?
- Thoughts about either treatment option?

Would you be willing for your child to take part in this trial?
Why?

## 1.3 Qualitative Study Topic Guide and Tools for Interviews

### 1.3.1 Risks and benefits prompt cards

LATER switch to oral antibiotics*
(Longer IV treatment)



| Benefits | Risks |
|---|---|
| • Guaranteed delivery of the antibiotic<br>• Treatment not dependent on child being willing to take medicine (or on remembering doses)<br>• No drug gut absorption problems that sometimes happens in very ill children<br>• Reliable treatment of the infection | • More time in hospital or under community nurse team<br>• Disruption of daily activities<br>• Risk of infection at site of IV line<br>• Risk of displaced or blocked lines<br>• Increased risk of reaction to antibiotic<br>• Increased risk of side effects such as bone marrow suppression |

*Switch only made once pain, fever and infection (measured by a blood test) is reduced.

## EARLY switch to ORAL antibiotics*
## (shorter period of IV)

### Benefits

- Shortened stay in hospital (or daily visits by community nurse to give intravenous antibiotics)
- Reduced risk of infection at site of intravenous line (where drug is administered)
- Avoids problems with displaced or blocked lines
- Lower risk of reaction to antibiotic and side effects

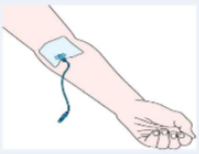
### Risks

- Reduced IV therapy may result in incompletely or inadequately treated bone or joint infection
- Incompletely or inadequately treated infection may rarely lead to chronic infection with destruction of cartilage, bone and growth plate, which can then cause permanent deformity and disability.

* Switch only made once pain, fever and infection (measured by a blood test) is reduced.

1.3.2 Risks and benefits prompt cards 8-12 years

## Longer IV (like treatment A)



### Advantages

- Drug goes straight into your blood and treatment is reliable
- Don't have to remember to take it, or take medicine that tastes horrible!

### Disadvantages

- More time in hospital or visits from nurse at home.
- You can get infections from the tube
- The tube might get blocked or knocked out of place.

## Shorter IV (like treatment B)

### Benefits

- Less time in hospital, or having nurse visit at home
- Can't get infections , blocked or knocked out of place (like a tube can!)

### Risks

- May forget, or not want to take it
- This means the illness might not get completely better -
- Which could mean long term problems or disability.

### 1.3.3 Topic guide Children 4-7 years

CHILDREN 4-7
(using one 'patient' teddy/toy and one 'doctor' teddy/toy).

***First section***
*This first bit of the interview is all about YOU and OM/SA.*

1. What it was like for you when you were poorly with OM/SA? How did it make you feel?
    - What was it like staying in hospital? PROMPT on whether mum/dad etc. could stay and how that was for them.

***Second section***
*This part of the interview is to ask what YOU think about how the doctors found out your illness and explained it to you. I've brought a doctor friend of mine along to help with the questions (show teddy/toy doctor).*

2. What did the doctor *(show toy)* do to find out was wrong with you? (like tests or anything? )
- What was that like? PROMPT for feelings, experiences.

3. How did the doctors *(show toy)* explain the illness?

4. What treatments did the doctor talk about?
- What did you feel about them?
- What would have happened without the treatment?

***Third section***
*In this part I would like to ask what it was like to have the different types of treatment for your illness.*

5. Did you have to have any operations?
- What were they for?
- What was it like to have those/that operation? How did you feel before/after?

*The type of medicine that you were given is called antibiotics and the doctors gave it to you in two different ways. First of all you were given the antibiotic medicine into your blood, through a tube which looks like this (show picture of cannula/PICC) and then you were given them to take as a medicine, like this (show picture of oral antibiotic):*

6. This teddy (introduce patient teddy) has got the same illness that you had and has to have some antibiotics. Could you tell teddy what it is like to have this type of antibiotics (*put IV by 'patient' teddy*)?
- What will he like about it and what won't he like? **PROMPT**: hospital stay? Nurse giving IV? Waking up at night?

7. And how about this type of antibiotic (give 'patient' teddy the antibiotic bottle)?

- What was good and bad about this one? **PROMPT**: taste, remembering to take it.

*8.* Why did the doctors give you (and teddy!) this first (*show IV prop/picture*) and then this? (*show oral prop/picture)*

9. Which way treats the illness best?

- PROBE which one/why? What makes you say that?

10. When they were helping you, what did the doctors and nurses do well?

11. What would you like done differently or better?

12. Do you feel completely better from OM/SA now? (Yes/No) Why?

13. Do mum and dad (relevant adult) think you are completely better now? Why?

### 1.3.4 Topic guide Children 8-12 years

CHILDREN 8-12

***First section***
*This first bit of the interview is all about YOU and OM/SA.*

1. What it was like for you when you were poorly with OM/SA? How did it make you feel?
    - What was it like staying in hospital? PROMPT on whether mum/dad etc. could stay and what that was like for them.

***Second section***
*This part of the interview is to ask what YOU think about how the doctors found out your illness and explained it to you.*

2. What did the doctors do to find out was wrong with you? (like tests or anything? )
What was that like? PROMPT for feelings, experiences.

3. How did the doctors explain the illness?
- What was it like to learn you had this illness?

4. What treatments did the doctor talk about? (Did they talk to you as well as your mum and dad?)
- What did you feel about them?
- What would have happened without the treatment?

***Third section***
*In this part I would like to ask you what it was like to have the different types of treatment for your illness.*

5. Did you have to have any operations?
- What were they for?
- What was it like to have those/that operation? How did you feel before/after?

*The type of medicine that you were given is called antibiotics and doctors gave it to you in two different ways. First of all you were given the antibiotic medicine straight into your bloodstream, through a tube which looks like this (picture of cannula/PICC), and then you were given them as a liquid like this (show picture of oral antibiotic):*

6. What was it like having to have this type of antibiotic (show picture/prop of IV antibiotic)
    - Can you say what was good about it and what wasn't good about it? **PROMPT:** hospital stay? Nurse giving IV? Waking at night?

7. And how about this type of antibiotic (show picture/prop of oral antibiotic)?

- What was good and bad about this one? **PROMPT**: taste, remembering to take it, waking at night?

8. Why did the doctors give you this first (show IV picture) and then this? (show oral picture)

9. Which way do you think treats the illness best?
   - PROBE which one/why? What makes you say that?

10. Do you feel completely better from OM/SA now? (Yes/No) Why?

11. Do mum and dad (relevant adult) think you are completely better now? Why?

**Fourth section**
In this final section, I would like to ask you what you think about an idea that doctors have to compare two different types of treatments for this kind of illness, in a kind of test. This test would help doctors to find out the very best treatment for children who have bone or joint infections. As you have had already had OM/SA your opinions would be very helpful to us.

Here is a picture which explains what would happen if a family and a child are asked if they want to take part in this kind of test. SHOW PROCESS DESIGN FOR RCT 8-12 YRS and talk through it.

First of all the test l is explained to the child and their family. Then they have time to think whether they want to take part or not. If they don't want to take part that is absolutely fine. If they do want to take part, then a computer (that doesn't have any information about the child) decides WHICH treatment the child would receive. The main difference in this test is to do with how long the child would stay on IV antibiotics, that is the antibiotics given through a tube. You can see the different options in the picture.

12. Do you have any questions or comments about the test?

Let's have a look at the questions on this sheet together and see if you can answer them. Allow child to read (or read out depending on age) the questions on the sheet Process Design for RCT 8-12 years. Go through each in turn, seeking responses.

- What information would you need about the test?
- Who should give you this information?
- Who would you talk to about it?
- How would you feel about a computer deciding which treatment?
- Which treatment is better?
- Would you like to take part in this test? Why

13. Just to finish, here is a card that shows the advantages and disadvantages of staying on IV antibiotics for a long time. SHOW CARD 8-12 years. Allow child to read, or read to them.
    - Having seen those, would you like to take part in this test ? *Probe reasons for any changes in/maintenance of original decision. (Explain/reassure afterwards, as necessary, that this is only a theoretical question. Not actually requesting participation.)*

## 1.3.5 Topic guide Adults Version 7 15/01/2015

Adult (and 13 +) Interview guide

1. I would like to understand what it was like for you when your child first got ill with SA/OM. Could you tell me about the condition and how it affected them?

2. And please could you tell me how the condition was *diagnosed*?

3. What did you understand about:
    a. longer term impacts of the condition?
    b. possible complications of the condition?
    c. the treatment options available?
    d. and how did you feel about these?

4. Could you talk me through the different treatments that your child received (including any operations and antibiotics?) What was the order in which those treatments were given?
    *PROMPTS as relevant*
    a. Operation – number/ purpose?
    b. Antibiotic – how was this administered to your child IV (drip, driver etc.)/Oral?
    c. Location of treatment (hospital/home)

SCRIBE ON TIMELINE

"*I would like to ask you in more detail about the different methods for giving antibiotics, that is intravenously (straight into the blood stream), and orally – shown on the timeline here.*"

5. Could you tell me what is was like for you and your child, when the IV antibiotics were being administered, for (time indicated on timeline) weeks? *(e.g. ease or discomfort of treatment, experience of being in hospital etc.)*
    Then (if not covered above) –
    a. What did you understand about the clinical reasons for, or the advantages of, the use of IV antibiotics?
    b. What were the advantages for you and your child?
    c. What did you understand about the clinical disadvantages of using IV antibiotics?
    d. What were the disadvantages for you and your child?

6. And could you tell me now about your child's treatment with oral antibiotics? What was this part of the treatment like for you and your child? *(e.g. release from hospital, adherence etc)*
    Then (if not covered above)
    a. What did you understand about the clinical reasons for, or the advantages of, oral antibiotics?
    b. What were the advantages for you and your child?

c. What did you understand about the clinical disadvantages of using oral antibiotics? What were the disadvantages for you and your child?

7. Thinking about the point when the switch was made from intravenous antibiotics to oral antibiotics – here (indicate on timeline). What was the reason for the switch being made for at that point?

    a. How (and by whom?) was the decision about the switch made? Did you and your child contribute to that decision?
    b. Were you happy with the decision to switch at that point? Why?

8. Looking at the timeline, what do you think about the length of the treatment period overall?
    a. Could it be shortened and what risks/advantages might this carry?

9. We've spoken about how you knew your child was becoming unwell. Could you tell me about any other problems/symptoms that your child experienced during the course of their illness and treatment? WHEN they happened? What did you think was causing these symptoms?

10. Could you tell me now about signs that showed you your child was getting better? What did you think was bringing about these improvements?

11. We've spoken about how your child was feeling during the course of their illness. I'd like to ask you about your feelings – could you run me through how you were feeling from when you noticed your child was getting ill, through treatment and finally to recovery?

12. How successful do you feel your child's treatment has been overall and why? *(Prompt side effects/complications)*

    a. What are the factors that are most important to you in judging whether treatment has been successful? (PROMPTS: recovery? Time in hospital? Pain? Ease of giving treatment?)

*"In this final section, I would like to ask your views about a possible clinical trial to determine the best course, combination and duration of antibiotics, for this type of infection. For this type of trial, doctors would need to recruit children with a bone/joint infection to take part. Would you mind having a read through this brief background information, and then I will ask you a few questions about it."*

SHOW PROMPT BACKGROUND TO TRIAL SHEET AND TRIAL PROCESS DIAGRAM (SEE SEPARATE ATTACHMENTS)

13. Would you mind taking a few minutes to look at this diagram? In the middle it shows the basic process that families would follow from being invited to take part in a trial through to their decision to participate or not. I would like to hear your comments about the various aspects of this process.

Then (as necessary – also referring to questions shown on RCT process sheet)

a. Is there anything that you don't understand?
b. Initial reactions?

WORK THROUGH QUESTIONS ON SHEET TOGETHER

14. I'd like to ask you to think back to when your child had first been diagnosed with this condition. How would you would have felt if your doctor or nurse approached you at this point to discuss a research study?
    a. What factors would affect your decision making?
    b. What advice would you give to a friend with a child in the same position?

15. We were talking earlier about the advantages and disadvantages of IV and oral antibiotics. Just to finish, this card shows the 'clinical' advantages and disadvantages of an early switch to oral antibiotics in the treatment of bone and joint infections. SHOW CARD.
    a. Which of these (if any) particularly strike you? Which ones would be important to you and your family?
    *b.* Having been made aware of this information, would you be willing for your child to take part in this trial? *Probe reasons for any changes in/maintenance of original decision. (Explain/reassure afterwards, as necessary, that this is only a theoretical question. Not actually requesting participation.)*

## 1.4 Patient information sheets

### 1.4.1 Patient information sheet Parents

# THE DINOSAUR STUDY
## (CHILDREN'S BONE AND JOINT INFECTION STUDY)

**Parent Information Sheet**

**Qualitative Sub-study**

**Version 1.1 Dated 27-08-2014**

**(www.dinosaur-study.org.uk)**

Thank you very much for participating in the DINOSAUR microbiology sub-study.

We would now like to invite your child to take part in our qualitative research study. Before you decide we would like you to understand why the research is being done and what it would involve for you and your child. One of our team will go through this information sheet with you and answer any questions you may have.

### Why is this study needed?

As you may know, the best duration of antibiotics for bone and joint infections is not known, and we would like to find out whether shortened courses of antibiotics are safe and effective. The DINOSAUR study will give us some information about this, as many hospitals are already giving shorter courses of intravenous antibiotics, and using oral antibiotics when there is improvement in the child's condition. This may have been the case with your child's treatment.

This part of the study is to find out about parents' and children's understanding of bone and joint infection. We would like to find out more about your personal experiences and about your understanding about the risks and benefits of different types of treatment. We would also like to know about your experience and understanding of research.

### Why has our family been chosen?

You were approached because you participated in the DINOSAUR microbiology sub-study, providing small amounts from your child's existing samples for extra testing. At the time of consent you agreed to be approached for this qualitative study. If you do not want to participate, please let us know and we will not contact you again.

### What will happen if we join the study?

A questionnaire has been prepared by a qualitative researcher. This will be used by the researcher to speak to you and your child about their experiences and understanding of bone and joint infections, and of research. The discussion between you and the researcher will take approximately

Contact: Dr Priya Sukhtankar, Mailpoint 218, Wellcome Trust, University of Southampton NHS Foundation Trust, Tremona Road, Southampton SO16 6YD
Email: dinosaur.study@liverpool.ac.uk

between 30 minutes and two hours (depending on how much you would like to discuss) and can be done at a time and place that is convenient to you and your child.

**Consent:**

If you and your child are happy to take part, you will be asked to sign a consent form on behalf of your child before they take part. You will get a copy of the signed consent form and information sheet to keep. Your child will also be given information about the study in a format appropriate to their age group.

**Are there any risks or benefits to my child if they join the study?**

It is unlikely that the study will help your child but the information we get might help treat children with bone and joint infections in the future.

**Will anyone else know my child is taking part in this study?**

Yes. Only people working on the study or working to ensure the study is run correctly will have access to the data. All information will be made anonymous before publication. All information collected about your child during this study will be confidential and will be handled, stored and destroyed in accordance with the Data Protection Act 1998.

**What if there is a problem?**

There are no risks to your child's health by participating in this study. If you or your child has any concerns about any aspect of this study, you should speak with the qualitative researcher, or contact the DINOSAUR study team via the DINOSAUR website (www.dinosaur-study.org.uk). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

**Who is doing this study?**

The study is funded by the Department of Health (National Institute of Health Research Health Technology Assessment Programme). It is being run in the hospital where your child is being treated, and is being organised by The University of Southampton, University Hospital Southampton NHS Foundation Trust and the University of Liverpool. This research has been approved by a research ethics committee, who are happy that the study is being conducted in an appropriate manner. This study is also supported by the Medicines for Children Research Network (www.mcrn.ac.uk).

**THANK YOU FOR READING THIS INFORMATION SHEET.**
**WE HOPE YOU HAVE FOUND THIS SHEET HELPFUL**

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## 1.4.2 Patient information sheet Child



# THE DINOSAUR STUDY
## (CHILDREN'S BONE AND JOINT INFECTION STUDY)

**Child Information Sheet**

**Qualitative Sub-study**

**Version 1.1 Dated 27-08-2014**

**(www.dinosaur-study.org.uk)**

Thank you very much for participating in the DINOSAUR microbiology sub-study.

### What is a qualitative study? Why is this being done?

Research is what you do when you want to learn about something or find out something new. Qualitative research means that we ask people who have experience of being sick and then being treated about what it was like, and what they have learned from it so that we can learn from it too.

### Why have I been chosen?

You are being asked to take part in this study because you had a bone or joint infection and were treated in hospital. You very kindly helped us by taking part in another study looking for germs in your blood and throat. We would like to know what all of this was like for you.

### Do I have to help?

No, if you and your mum and dad don't want to do this then you don't have to.

### What will happen to me if I say yes?

If you are able you will be asked to write your name on a form. This is to say that you understand the study and what will happen. You will be given your own form to keep, as well as this leaflet. This is all you need to do.

A person who knows all about qualitative research will come to see you and your mum and dad to talk about what happened when you

were in hospital and what you understand about the treatment and the research. They will ask you some questions about this. It will take about half an hour, but maybe longer if you and your parents have more to say.

## Will anything good happen to me if I take part?

No, we will be very grateful for your time, and what you tell us may help other children who have bone and joint infections in future.

## Will anything bad happen to me if I take part?

No, this is not a test.

## What do I have to do now?

If you have any questions you can ask the qualitative researcher, or ask your mum and dad to explain this leaflet to you. If you say yes then all you have to do is meet the qualitative researcher at a time and place that is easy for you, and spend half an hour talking to her/him.

## 1.5 Consent forms

### 1.5.1 Parent consent form

# THE DINOSAUR STUDY

## (CHILDREN'S BONE AND JOINT INFECTION STUDY)

### Qualitative Sub-study

**Parent Consent Form Version1.0 07-07-2014**

www.dinosaur-study.org.uk

| | | Please initial box |
|---|---|---|
| 1. | I confirm that I have read and understand the information sheet dated **27-08-2014 (version 1.1)** for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. | |
| 2. | I understand that participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my or my child's care or legal rights being affected. | |
| 3. | I understand that data collected during the study may be looked at by responsible individuals from the research team, regulatory authorities, sponsor or from the NHS Trust, where it is relevant to me and my child taking part in this study. | |
| 4. | I understand that qualitative data will be collected for this study and may be used to develop new research and that data protection regulations will be observed. | |
| 5. | I agree for my consent form and my child's details, which will include my child's name, to be passed to the Medicines for Children Research Network Clinical Trials Unit for the administration of the study. | |
| 6. | I give permission for a qualitative researcher to interview me and my child. | |
| 7. | I agree to medical personnel, responsible for my child's welfare, being informed of our participation in the study. | |
| 8. | I agree to take part in the above study. | |

| | | |
|---|---|---|
| _____ | _____ | _____ |
| Name of Parent / Guardian | Signature | Date |
| _____ | _____ | _____ |
| Researcher | Signature | Date |

**When completed, 1 (original) to be kept in medical notes, 1 for parent/guardian, 1 for researcher site file; 1 for the MCRN CTU, University of Liverpool**

1.5.2 Assent form



**THE DINOSAUR STUDY**

**(CHILDREN'S BONE AND JOINT INFECTION STUDY)**

**Qualitative Sub-study**

**Children's Assent Form Version1.1 10-09-2014**

**www.dinosaur-study.org.uk**

| | Please initial box |
|---|---|
| 1. I have read and understand the information sheet dated **28-08-2014 (version 1.1)** for this study. I had time to think about it and to ask questions | |
| 2. I understand that it is up to me whether or not I take part and that I can change my mind at any time. | |
| 3. I understand that I will be interviewed, and a researcher will ask me questions about having a bone and joint infection. | |
| 4. I understand that the information from my interview will be used to learn about bone and joint infections in children, and that other researchers will be able to see this information. | |
| 5. I agree to take part in the DINOSAUR Qualitative study. | |

| | | |
|---|---|---|
| Name of Child | Signature | Date |
| Researcher | Signature | Date |

**When completed, 1 (original) to be kept in medical notes, 1 for parent/guardian, 1 for researcher site file; 1 for the MCRN CTU, University of Liverpool**