

## Supplementary File 1. Example Topic Guide Questions

**Table 1.** Example interview topics and questions

Interview topics	Example questions
<b><u>PARENTS</u></b>	
<b>Background and experience</b>	<p><i>So just to get a background of what happened, what first prompted you to seek medical help when your child became unwell? (Prompt: explore what happened, how they were admitted to hospital)</i></p> <p><i>Has your child had a severe infection before this episode?</i></p> <p><i>Did the doctor give your child a diagnosis (e.g. did they tell you what had caused the illness?)</i></p>
<b>PiC Study consent process</b>	<p><i>Would you mind if I start by getting an overall picture of what happened when you first heard about the PiC Study... could you tell me a bit about that?</i></p> <p><i>At any point, were you aware of the clinical team mentioning PiC? If Yes, can you tell me a little bit more about this? How did this make you feel?</i></p> <p><i>Did the researcher check with you that it was a good time to talk about research?</i></p> <p><i>Was there anything that you found: a) unclear b) surprising?</i></p> <p><i>Did you have the opportunity to ask any other questions about the study? Did you ask any?</i></p>
<b>Research without prior consent</b>	<p><i>Families involved in PiC provided consent after their child was tested for infection (within 24-48 hours). We call this deferred consent or also known as research without prior consent. There is specific legislation in place to allow for this type of research. This is because in emergency situations there's not time to have a discussion about the research and that actually having that discussion might delay important treatment.</i></p> <p><i>What do you think about the use of research without prior consent in an emergency situation (for example, when a child has entered hospital via A&amp;E or born very early)?</i></p> <p><i>How did the nurse/doctor explain RWPC to you? Was it explained clearly? If not, provide explanation. Check understanding.</i></p> <p><i>What did you think when you found out that your child had already been entered into the study before you were approached by the doctor or nurse about your consent?</i></p>

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**Decision making**

*In making the decision about your child's participation in PIC, what sort of things went through your mind?*

*Could you tell me if you found anything about the study unclear or confusing?*

*Was there anything you found particularly helpful in making up your mind?*

*Was there anything specific that influenced your decision?*

*Would you mind telling me what were your reasons for (providing consent/not providing consent)?*

*Did you feel that your child may benefit from taking part in the study?*

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**Child assent**

*Did the nurse or doctor explain the PIC study to your child and give them an information sheet to seek their permission to take part? IF YES:*

*a) Could you tell me a bit more about that?*

*b) Did they ask any questions?*

*What do you think involving children more in making the decision about the use of their information in a study?*

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**CLINICIANS****Professional role and involvement in PIC**

*What is your profession? (Explore: junior nurse, senior nurse, junior doctor, senior doctor)*

*How would you describe your role and what you have contributed to the PIC study?*

*(Explore: screening patients, helping with randomisation or consenting)*

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**Patient identification and recruitment**

*Who would usually identify patients for inclusion?*

*Do you think the identification process could be improved?*

*Were there any barriers to recruitment?*

*E.g. Time, equipment failure, lack of training?*

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**Research without prior consent**

*Before PIC, did you have any experience of research without prior consent?*

*What were your initial thoughts when you first heard that the PIC study was to use a RWPC approach? [Prompt: Did you have any concerns?]*

*Have your views about research without prior consent changed over time?*

*If yes, could you tell me a bit more about that?*

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*At what point did they change before/after SIV? After experience of RWPC?*

*Have you had direct experience of discussing the study with parents and seeking permission to use their child's data in PIC?*

*If yes, could you describe to me what happens when a patient included and you are preparing to approach the parents?*

*Explore:*

- *At what time (post inclusion) have you usually approached parents? (Explore minimum and maximum time frames)*
- *What do you look for when establishing when best to approach parents?*
- *Do you speak to the clinical care team?*
- *Have you ever asked the clinical team to introduce you to the parents?*
- *Are there ever any times when you've identified an eligible child but you feel it might not be appropriate to approach the family?*

*How have parents reacted to finding out that their child has been entered into a clinical study without their prior consent?*

*Explore: Have any parents been angry/ upset etc. What happened?*

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**Child assent**

*Have you involved children in PIC discussions?*

*Explore: barriers and whether age appropriate PIS have been given/ taken home?*

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## Supplementary File 2. Approach to qualitative data analysis

<b>Phase</b>	<b>Description</b>
<b>Transcription and data cleaning</b>	Interviews transcribed by a professional audio typist and were checked for accuracy. Personal information ( <i>e.g.</i> names) were removed to ensure anonymity.
<b>Familiarising with data and generating initial themes</b>	TW read and re-read a sample of transcripts noting down initial ideas around main themes and potential codes.
<b>Developing the coding framework</b>	Using NVivo 12 Software, TW created codes for initial main themes ( <i>e.g.</i> , thoughts on PiC; thoughts on RWPC; decision-making in the emergency setting; and misunderstandings and misconceptions) and began developing a coding framework using line by line coding, comparing between transcripts as part of a constant comparative approach
<b>Initial coding meeting</b>	TW and KW met to discuss early themes and develop the coding framework.
<b>Second coding</b>	KW second coded a sample (3 parent and 2 clinician interviews; 25%,) of transcripts and made notes on any new themes identified and how the framework could be refined.
<b>Second coding meeting</b>	TW and KW met to discuss, reflect and refine the specifics of each theme in the coding framework.
<b>Completion of coding of transcripts</b>	TW completed coding of all transcripts in preparation for write-up.
<b>Write-up and final revision of coding</b>	TW and KW developed the manuscript using themes to relate back to the study aims ensuring key findings and recommendations were relevant to the PiC trial design and RWPC in studies of diagnostic test accuracy. Final discussion and development of selected themes occurred during the write-up phase.

**Supplementary File 3.** Selected quotations from parents by theme

Theme	Sub-theme	Example quotes
<b>Support for research</b>		<p>“I felt that it was a good idea maybe you know to help other children” (P3 Mother)</p> <p>“I’m all for research” (P15 Mother)</p> <p>“Yes I do absolutely. Given the opportunity I think it's important because if it helps some other kid then that has to be a positive thing” (P10 Mother).</p>
		<p>“Yeah, I think I'd be happy enough with it, I wouldn't have an issue afterwards you know” (P8 Mother)</p>
<b>Support for RWPC</b>	Suitable for emergencies	<p>“In an emergency it's fine” (P13 Mother)</p> <p>“I think the doctor should do what they can do as quick as they can” (P2 Mother)</p>
	If no harm to child	<p>“if the child isn't being tortured if you know what I mean” (P9 Mother)</p>
	See additional diagnostic tests as a potential benefit	<p>“Yeah so I thought they might be able to find something out” (P3 Mother)</p> <p>“Well maybe if it had it turned out to be anything sort of worse she probably would have benefited from it.” (P6 Mother)</p> <p>“I think if it was going to be like beneficial for [Name] to have a test that would bring back results quickly” (P7 Mother)</p> <p>“My children benefited in that we knew straight away” (P8 Mother)</p> <p>“That said parents do really appreciate getting that result and that negative rather than waiting a few days in the lab.” (C2 Senior Doctor)</p> <p>“It was instant really that the results came back...I just thought that was a great thing.” (P5 Mother)</p> <p><i>“we would find out within a few hours if it was meningitis” (P8 Mother)</i></p>

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	No perceived harm	<p>Interviewer” Did you envisage any possible risks for [Child Name] taking part in the study?  Parent “No not at all” (P12 Father)  “I think these tests can be done just as part of a blood sample anyway, I think I would say no, it’s fine the way it’s (RWPC) done” (P14 Mother)  “I know you’re not doing any extra harm physically” (C2 Senior Doctor)</p>
<b>Timing of consent discussions is important</b>	Do not approach immediately at presentation	<p>“For me I would say that maybe a wee bit of respect should be given because at the end of the day if you’re in you’re trying to find out about your child, I personally probably wouldn’t have went for it because I will be thinking you know I’m trying to sort out my child here to see what’s wrong with them and I have somebody coming in to try and talk about a study. I don’t think there would be much consideration for the parents and the child at the time” (P3 Mother),</p>
	Don’t have capacity to think about research during the initial emergency	<p>“Well you’re definitely not taking it in, you’re just more concerned that your child is going to get better” (P2 Mother).</p>
	Approach after the initial emergency is favourable	<p>“I got the letter and I could make a decision in a calm environment (P 10 Mother)”</p>
	Clinicians appropriately timed consent discussions	<p>“It would be a little bit of time after I had taken the samples and made sure that the child was well and stable” (C4 Senior Doctor)  “I will go up and speak to the nurse or a member of the nursing staff and ask how the patient was doing and whether they felt it was appropriate and usually I got the nurse to introduce me” (C3 Junior Doctor)  “I would be very much led by the parent” (C2 Senior Doctor).</p>
<b>Decision making</b>	The decision to participate was easy	<p>“I mean it was a complete no-brainer.” (P12 Father)  “Being bluntly honest it wasn’t, as soon as it was mentioned we were more than happy to go ahead that was really it.” (P1 Father)  “Parents are really positive and often ask me why we even need consent. They say its fine to use the data” (C2 Senior Doctor)</p>

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	<p>“I think it was all pretty clear from what [Clinician Name] said and what was on the form” (P6 Mother)</p> <p>“it was just a there and then kind of decision” (P11 Mother)</p> <p>“it was positive and if anything, people are quite quick to agree to it (C4 Senior Doctor)”</p> <p>“all parents wanted to be on the study” (C1 Research Nurse)</p>
Should discuss severe infection prior to the research team approaching	“It's a bit worrying when you hear it like that” (P7 Mother)
Parents do not show a preference for who should consent e.g. nurse/doctor/researcher	“Anybody really it doesn't have to be a doctor it wouldn't matter if it was the doctor or the nurse but just someone with a professional manner” (P3 Mother)
Parental understanding of the study was good	<p>“From what I remember it was, I could be totally wrong, it was a test, a swab on the back of the throat and it's a way of getting results back sooner to look for infections or whatever because the blood tests that they do take 48 hours and so as far as I know this is a test to try and get results back sooner, within 30 minute” (P15 Mother)</p> <p>“They all seem to understand it well” (C5 Senior Doctor)</p>
Decision hadn't changed over time	“Yes I'm still happy with my decision I think it was the right decision.” (P10 Mother)
No pressure	<p>“Yeah well when I got the phone call it was basically asking did I want to take part in it and you were given the option there whether you were wanted to or not. So for me if I didn't want to take part in it well you have an option” (P3 Mother)</p> <p>No not at all no, it didn't feel pressured in either way to be honest with you no.” (P14 Mother)</p>
Parents recommend including children in the consent process where appropriate	“If they understand and they are old enough to comprehend, then I don't see a problem with them having an input as well because if they're old enough to make their own mind up then they should be given some say.” (P1 Father)

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**Using opt out alone  
not appropriate**

“It wouldn't be appropriate for extra procedures done that weren't to the benefit of the child” (P12 Father)

“No I think probably it would be better to discuss it with the family”(P15 Mother)

“I would have just stayed in the study.” (P15 Mother)

“I think if I had any concerns it would have been more difficult to ask them”(P10 Mother)

” “I feel it's a wee bit cold perhaps”(P10 Mother)

Would still take part  
though

Harder to raise concerns

A little “cold”

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