**Parents’ and clinicians’ views on conducting paediatric diagnostic test accuracy studies without prior informed consent. Qualitative insight from the Petechiae in Children study (PiC)**

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# Abstract

**Objective** The Petechiae in Children (PiC) study assesses the utility of presenting features and rapid diagnostic tests in the diagnosis of serious bacterial infection in feverish children with non-blanching rashes. An embedded qualitative study explored parents’ and clinicians’ views on the acceptability of the PiC study, including the use of research without prior consent (RWPC) in studies of diagnostic test accuracy.

**Design** Semi-structured qualitative interviews. Analysis was thematic and broadly interpretive, informed by the constant comparative approach.

**Participants** Fifteen parents were interviewed 55 (median) days since their child’s hospital attendance (range 13 to 95). Five clinicians involved in recruitment and consent were interviewed.

**Results** Parents and clinicians supported RWPC for the PiC study and future emergency paediatric diagnostic test accuracy studies,as long as there is no harm to the child and emergency care is not delayed. Parents and clinicians made recommendations around the timing and conduct of a consent discussion, which were in line with RWPC guidance. Parents enrolled in the PiC study preferred a design which included consent discussions with the research team over the alternative of “opt-out” consent only.

**Conclusions** This embedded qualitative study demonstrates that RWPC is appropriate for use in paediatric emergency studies of diagnostic test accuracy and that the approach utilised in PiC was appropriate. Future diagnostic studies involving additional invasive procedures or an opt-out only approach to consent would benefit from exploring parent and clinician views on acceptability at the pre-trial stage.

**Trial registration number** ClinicalTrials.gov Identifier: NCT03378258

**Introduction**

Early recognition of serious bacterial infections (SBI) in childhood improves outcomes [1–6], though clinical features are often indistinguishable from self-limiting viral illnesses during the prodromal phase [1, 2, 4]. Many children are therefore given precautionary broad-spectrum antibiotics; while safe in the acute phase, this is linked to emergence of antimicrobial-resistance [7–10]. Clinical decision makers often face dilemmas in balancing the need for prompt treatment against antimicrobial stewardship, and in determining which children can be safely discharged, though anxiety related to these issues may be reduced where reliable test results are available.

An ideal test should give quick and accurate results which provide a diagnosis and/or aid clinical decision making. It is now possible to perform rapid-diagnostic tests in the emergency setting, with results available within minutes. These have shown promise when tested under laboratory conditions or using retrospective case-control methodology [11]. However to understand their true diagnostic accuracy and potential patient benefit they must be studied prospectively [11].

Studies investigating the diagnostic test accuracy (DTA) of rapid tests for SBI require research without prior consent (RWPC, also known as deferred consent) as the diagnosis and treatment of potentially life-threatening infections is time critical [12, 13], and by definition such studies are focused on obtaining very rapid test results. RWPC has successfully been used in paediatric emergency interventional studies, but there is a lack of knowledge about parent and clinician perspectives on the acceptability of RWPC in DTA studies[14–20]. Table 1 compares different models of consent including RWPC, prospective informed consent and opt-out consent.

The Petechiae in Children (PiC) study (summarised in Box 1) was designed in collaboration with Paediatric Emergency Research in the UK and Ireland (PERUKI), and the study protocol has been published [21, 22]. It is the largest study evaluating the assessment and management of feverish children with non-blanching rashes and is the first UK study performed since the introduction of the Meningococcal B and C vaccinations onto the UK vaccination schedule. It aims to provide more robust evidence for those making decisions in the clinical care of these patients and includes evaluation of presenting features and point of care biomarkers. The PiC study opened to recruitment in November 2017, and enrolment is due to finish in June 2019. The objectives of the PiC study are to report on the diagnostic test accuracy of point-of-care testing for procalcitonin (PCT) and Neisseria *meningitidis* DNA, to validate existing clinical practice guidelines and the describe the aetiology of fever and non-blanching rash including the risk of serious bacterial infection such as meningococcal disease.

In this embedded qualitative study, we aimed to explore parents’ and clinicians’ views on the acceptability of the PiC study, including use of RWPC in DTA studies in emergency situations.

**Methods**

*Study Design*

The PiC study design (Box 1) utilises RWPC in accordance with clinical trials legislation and RWPC guidance[22–24]. The PiC study pilot took place at the Royal Belfast Hospital for Sick Children (RBHSC), a tertiary level children’s hospital in the United Kingdom.

Children were enrolled into the PiC study by the treating emergency clinician, and informed consent (Summarised in Box 1) sought after the clinical condition was stable. Written consent for the use of data was sought from participants either in the emergency department (ED), on the ward, or after discharge, depending on the timing of the presentation, clinical course, and timing of discharge [21]. Participants who were approached after discharge received an initial telephone call outlining the study and then a follow up postal consent.

*Recruitment and sampling procedure for embedded qualitative study*

Consent for participation in an embedded qualitative study was sought in writing as part of the PiC consent process and then verbally re-confirmed at interview. To ensure sample variance in this embedded qualitative study, we invited parents to interview who had been approached for consent at the three possible time points.

We used previous research [14–20] to develop interview topic guides (supplementary file 1), which contained open-ended questions and prompts to explore views and experiences of the PiC study, including use of a RWPC approach. TW (Male Paediatrician) received qualitative research training from KW (Female Social scientist). TW conducted semi-structured telephone interviews with parents of recruited children, as well as face to face interviews with PiC clinicians at the RBHSC. All clinicians involved in PiC recruitment or consent conversations at the RBHSC were invited for interview. Interviews were digitally audio recorded and transcribed verbatim by a professional audio typist. Transcripts were anonymised and checked for accuracy by TW. Interviews were conducted until data saturation (where no new major themes are identified in the analysis of data) [26, 27]. There were no repeat interviews or additional field notes recorded.

*Analysis*

TW led the analysis with assistance from KW. Analysis was thematic and broadly interpretive, informed by the constant comparative approach [28–33] (supplementary file 2). We used NVivo Version 12 software to assist with the organisation and coding of data.

*Study Registration*

Registered at <https://www.clinicaltrials.gov> (trial registration: NCT03378258) on the 19/12/2017.

*Ethical Approval*

The Northern Ireland Research Ethics Committee (REC) and the Belfast Trust IRB approved the PiC protocol, including the embedded qualitative research (REC Reference - 17/NI/0169)(IRB Reference 16201MS-SW).

**Results**

Between the 11th November 2017 and 31st July 2018, 147 of 150 eligible patients were enrolled in the PiC study at the RBHSC. One participant declined participation; two were not approached as an interpreter was not available. 131 patients (89%) agreed to telephone interview. The one parent that declined to participate in the PiC study also declined interview.

Data saturation was reached at 15 interviews (where no new major themes are identified in the analysis of data). Parent and patient characteristics are presented in Table 2. No participants knew TW prior to the interview. All invited clinicians (n=8) agreed to participate in a face-to-face interview, of whom six (75%) had previous experience with clinical research (Table 3). Data saturation was achieved at five interviews (one research nurse, one junior doctor, three senior doctors). Interviews lasted between 22 and 44 minutes (supplementary file 3 contains selected quotations by theme).

### *Opinions on RWPC in PiC and future DTA studies*

A definition of RWPC was read to participants (Box 2) who were then asked, “What do you think about the use of research without prior consent in an emergency situation?” All parents supported RWPC in PiC and future DTA studies, highlighting the need to avoid treatment delays *“I think the doctor should do what they can do as quick as they can*” (P2 Mother). Parents valued the speed of diagnostic tests which could be conducted alongside emergency clinical care: *“It was instant really that the results came back…I just thought that was a great thing”* (P5 Mother). However, three parents indicated that prior consent would be required for any research that involved additional interventions that would cause pain or discomfort, such as an additional *“pinprick”* (P9 Mother) for blood samples:

*“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)

Clinicians supported RWPC in PiC and future DTA studies, stating tests were quick, *“relatively easy”* (C3 Junior Doctor) to conduct, did not cause harm “*I know you're not doing any extra harm physically”* (C2 Senior Doctor), or involve *“any more invasive tests that you already would be doing”* (C5 Senior Doctor). Clinicians described parents’ positive responses to consent discussions and cited *“all parents wanted to be on the study” (*C1 Research Nurse*)* as an indicator of study and RWPC acceptability.

### *Timing of consent discussions*

Analysis of parent and clinician accounts of recruitment processes suggested that clinicians followed the study protocol and appropriately timed study discussions. Clinicians described how they would assess the ability of parents to discuss the study on the ward or in ED based on:the condition of the child: **“***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); discussions with clinical staff:*“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)**;** and perceived readiness of parents to discuss consent:*“I would be very much led by the parent”* (C2 Senior Doctor).

The majority (14 of 15) of parents advised against seeking consent prior to testing. They described how during the initial emergency parents would not have the capacity to discuss research as the priority is their child:“*you're just more concerned that your child is going to get better”* (P2 Mother). Some also stated that broaching a study at this time point could be perceived as disrespectful:

*“For me I would say that maybe a wee bit of respect should be given… 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.”* (P3 Mother).

### *Parental decision making and understanding of PiC*

The decision to provide consent for PiC was often described as being quick *“it was just a there and then kind of decision”* (P11 Mother) and easy: “*I mean it was a complete no-brainer*” (P12 Father). This was often attributed to the nature of the study, which parents perceived would not *“cause him any harm”* (P1 Father). Other reasons for consenting included parental support for medical research and a desire to help other children in the future. Parents also described how participation could help their own child, by enabling quick access to test results:

 *“I felt that it was a good idea maybe you know to help other children”* (P3 Mother)

*“I'm all for research”* (P15 Mother)

*“it was going to be like beneficial for [child name] to have a test that would bring back results quicker*” (P7 Mother)

*“we would find out within a few hours if it was meningitis”* (P8 Mother)

All parents interviewed (up to 3 months after discharge) remained happy with their consent decision “*I think it was the right decision*” (P10 Mother). During interviews parents were able to describe the study in detail and displayed good understanding. “*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*” (P15 Mother).

*Child assent*

Parents recommended including children in the consent process where appropriate, assuming they are old enough to understand the discussion. “*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)

However, parents and clinicians described how the majority of enrolled children were too young to participate in consent discussions. “*No they have all been little age, we did have one who was 5, he was at school. I did speak with him about the study with his parents there. I did offer them the assent form to have a look at, but he was fine and didn’t want to*” (C1 Nurse).

*Opt-out consent*

Clinicians stated that some families suggested consent discussions for this type of research were not required “*Parents are really positive and often ask me why we even need consent, they say it’s fine to use the data”* (C2 Senior Doctor). To explore this further, we sought parents’ views on an alternative approach, which would involve provision of a study information sheet and the option to opt-out of the PiC study (i.e. no full consent discussion with a member of the research team and the child’s data included in the study unless parents opted-out and chose for the data to be removed).

All parents stated that they would choose not to opt out: *“I would have just stayed in the study*” (P15 Mother). However, they stated that full consent discussions with families is preferable as the research team “*can explain more*” (P15 Mother). An opt-out approach that didn’t involve a full research discussion was viewed as impersonal: *“a wee bit cold perhaps”* (P10 Mother), and limited opportunities to discuss the study: *“I think if I had any concerns it would have been more difficult to ask them”* (P10 Mother). Parents enrolled in the PiC study preferred a design which included consent discussions with the research team over the alternative of “opt-out” consent only without any discussion: *“It wouldn't be appropriate for extra procedures done that weren't to the benefit of the child”* (P12 Father).

**Discussion**

This study provides insight into parents’ and clinicians’ views on the acceptability of RWPC in the PiC study and future DTA studies. Previously, parents’ views on their child’s involvement in a trial without their prior consent were unknown and clinicians were apprehensive about conducting RWPC [18,19]. Our findings are consistent with other successfully conducted clinical and qualitative studies that have demonstrated parent and clinician acceptability of RWPC in paediatric emergency medicine [12, 13, 17-19, 34–37]. Parents supported RWPC provided emergency care is not delayed and their child does not come to any harm [14, 17]. This finding was also supported by the high consent rate for use of data in the PiC study.

In line with RWPC guidance [38], clinicians assessed parents’ ability to discuss the study in collaboration with clinical staff and timed their consent approach appropriately. As in other studies, motivations for providing consent were often altruistic, such as to help others in the future and support research [17, 34, 35].

Rapidity of test results and the nature of additional interventions may influence parents’ views on the acceptability of RWPC in DTA studies. The PiC study and use of RWPC were acceptable to parents and clinicians as there were **no additional invasive procedures**. Similar concerns regarding additional phlebotomy events without prior consent were described by nurses and some parents involved in the CATheter infections in CHildren (CATCH) trial[18]. Future DTA studies involving invasive procedures or interventions in addition to usual clinical care would benefit from exploring parent and clinician views on trial acceptability and RWPC at the pre-trial stage.

Our findings in regard to opt-out consent for the PiC study were novel. Although some parents asked clinicians why consent was needed for the PiC study, when presented with a hypothetical alternative approach, parents favoured a full RWPC discussion with a member of the research team over provision of written materials and the opportunity to opt-out from having their child’s data included in the study. As consistently shown in previous studies exploring trial recruitment processes, parents valued conversations with clinicians above written information materials [14-20]. Parents stated they would not have opted out of the PiC study. However, only providing researcher contact details on written information sheet was viewed as impersonal and a potential barrier to voicing questions and concerns.

**Strengths and limitations**

Our findings fill an important gap in the existing literature by providing parent and clinician perspectives on RWPC for paediatric DTA studies. Our sample was limited as it involved parents and clinicians involved in the pilot phase. However, interviews were conducted until data saturation was reached and involved parents who experienced RWPC [32]. Interviews were conducted by TW who is the PIC study lead. TW was not known to parents or involved in their children’s clinical care. However, TW was previously known to clinicians and his non-independent role may have impacted upon their willingness to voice concerns about the study during interviews. Due to the high consent rate and no bereavements in the PiC study, our sample is limited to the views of parents who consented to the PiC study and whose children recovered. Finally, as children involved in the PiC study were typically under five years of age their views are not represented in our findings.

**Conclusion**

This study demonstrates that RWPC is appropriate for use in paediatric emergency diagnostic test accuracy studies not involving additional invasive procedures. Parents were supportive of RWPC for diagnostic test accuracy provided emergency care is not delayed and their child does not come to any harm. Future diagnostic studies involving additional invasive procedures or an opt-out only approach to consent would benefit from exploring parent and clinician views on acceptability at the pre-trial stage.

* “What is already known on this topic”
	+ Technological advances have resulted in a greater availability of rapid diagnostic testing for bacterial infection.
	+ The assessment of these tests in different diagnostic pathways is challenging; especially in the emergency setting where prior informed consent cannot be sought.
	+ No studies have explored the acceptability of RWPC for diagnostic test accuracy studies.
* “What this study adds”
	+ Research without prior consent is appropriate for diagnostic accuracy studies as long as the test is being used in an emergency situation and does not delay or interfere with urgent care.
	+ Consent discussions with a member of the research team are preferred to a written information only ‘opt-out’ approach.
	+ Future diagnostic test accuracy studies involving invasive procedures or interventions in addition to usual clinical care would benefit from pre-trial feasibility work incorporating parent and clinician perspectives.

**Declarations**

* **Ethics approval** The Northern Ireland Research Ethics Committee (REC) and the Belfast Trust IRB approved the PiC protocol, including the embedded qualitative research (REC Reference - 17/NI/0169)(IRB Reference 16201MS-SW).
* **Consent for publication** Not applicable
* **Availability of data and material** The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
* **Competing interests** None
* **Funding** This study was funded by the Public Health Agency of Northern Ireland (EAT/5313/16). The funder had no involvement in the design or conduct of the study.
* **Authors Contributions** TW, MDS, JM, DF, MDL, DR, KW conceptualised and designed the study. TW and KW completed analysis, drafted the initial manuscript. TW, MDS, JM, DF, MDL, DR, KW edited and approved the final manuscript as submitted. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.
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# **Tables:**

Table 1: Overview of consent models discussed in this manuscript

|  |  |  |  |
| --- | --- | --- | --- |
| Consent Model | Description | Rationale/Enablers | Considerations |
| Prospective informed consent  | Informed consent for participation in research is a key principle of good clinical practice. A potential participant (or parent/legal representative of a child) must be adequately informed about the research and their consent sought prior to their participation.  | Prospective informed consent helps protect an individual’s right to make an informed, un-coerced decision about their participation in research.  | Informed consent is not feasible or appropriate in certain situations, including emergencies. Without alternatives to informed consent emergency research could not be conducted and critically ill patients would not benefit from evidence- based healthcare. |
| Research without prior consent  | The research activity is performed and data are collected without prospective informed consent from the participant. Consent is sought to continue in the study at the earliest appropriate time (e.g. when the emergency situation has passed).  | Enables the conduct of vital research in emergency situations.  | Restricted to research, including drug trials in emergency situations where: the treatment is required urgently, it is not reasonably practicable to obtain consent prospectively and ethics committee approval has been given. |
| Opt-out consent  | Research activity is performed and data are collected. Informed consent is not sought but study information is provided including how participants can opt-out (e.g. decline to have their data included in the study). | Used in certain types of low risk studies, such epidemiological studies that do not involve additional procedures or change to clinical care.  | Studies utilising opt-out only have to provide clear justification to an ethics committee. Opt-out is not suitable for studies such as drug trials or research involving additional interventions or changes to clinical care.  |

Table 2: Summary Data (Parents)

|  |
| --- |
| Recruited Parents Summary Data |
| Fathers | 2 (13%) |
| Mothers | 13 (87%) |
| Median Time to Interview | 55 Days (Range 13 to 95) |
| Median Length of Stay | 2 Nights (Range 0 to 5) |
| Consent Route | Emergency Department n= 5Ward n=6After Discharge n=4 |
| Final Diagnosis | Viral Illness 7Group A Streptococcus 5Pneumonia 1Febrile Convulsion 1Reactive Arthritis 1 |

Table 3: Summary Data (Clinicians)

|  |  |
| --- | --- |
|  |  |
| Experience  | Have Previous Research Experience | 75% |
| Study Responsibilities | ScreeningConsentPOCT CRF Completion | 100%100%100%40% |
| Role | Research NurseSenior DoctorJunior Doctor | 20%60%20% |

POCT = Point-of-Care Testing, CRF = Case Report Form

Box 1:

* ***The Petechiae in Children (PiC) study aims to; determine the diagnostic accuracy of point-of-care testing for identifying children with serious bacterial infection, to validate clinical practice guidelines and to describe the aetiology of fever and non-blanching rashes in children.***
* ***The rapid point-of-care tests included molecular testing for Neisseria Meningitidis DNA on a throat swab and measurement of blood procalcitonin levels using 0.5ml of whole blood.***
* ***There were no additional phlebotomy events, to obtain the additional 0.5ml of blood required for PiC, beyond those needed for routine care.***
* ***Consent to include test result data and data from the attendance in the PiC study was then sought at the earliest appropriate opportunity. This was either during the inpatient stay, or after discharge depending on the timing of the presentation, clinical course and timing of discharge.***

Box 2:

***Families involved in PiC provided consent after their child was tested for infection (within 24-48 hours). We call this deferred consent or research without prior consent.***

***There is specific legislation is 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.***