


# Pilot feasibility study of a digital technology approach to the systematic electronic capture of parent-reported data on cognitive and language development in children aged 2 years

Neena Modi,<sup>1</sup> Ricardo Ribas ,<sup>1</sup> Samantha Johnson,<sup>2</sup> Elizabeth Lek,<sup>3</sup> Sunit Godambe,<sup>4</sup> Edit Fukari-Irvine,<sup>5</sup> Enitan Ogundipe,<sup>6</sup> Nora Tumor,<sup>6</sup> Nayan Das,<sup>7</sup> Abinithya Udayakumaran,<sup>7</sup> Becky Moss,<sup>8</sup> Victor Banda,<sup>1</sup> Kayleigh Ougham,<sup>1</sup> Victoria Cornelius,<sup>7</sup> Anusha Arasu,<sup>9</sup> Steve Wardle,<sup>10</sup> Cheryl Battersby,<sup>8</sup> Amanda Bravery<sup>7</sup>

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For numbered affiliations see end of article.

**Correspondence to**  
Professor Neena Modi;  
[n.modi@imperial.ac.uk](mailto:n.modi@imperial.ac.uk)

## ABSTRACT

**Background** The assessment of language and cognition in children at risk of impaired neurodevelopment following neonatal care is a UK standard of care but there is no national, systematic approach for obtaining these data. To overcome these challenges, we developed and evaluated a digital version of a validated parent questionnaire to assess cognitive and language development at age 2 years, the Parent Report of Children's Abilities-Revised (PARCA-R).

**Methods** We involved clinicians and parents of babies born very preterm who received care in north-west London neonatal units. We developed a digital version of the PARCA-R questionnaire using standard software. Following informed consent, parents received automated notifications and an invitation to complete the questionnaire on a mobile phone, tablet or computer when their child approached the appropriate age window. Parents could save and print a copy of the results. We evaluated ease of use, parent acceptability, consent for data sharing through integration into a research database and making results available to the clinical team.

**Results** Clinical staff approached the parents of 41 infants; 38 completed the e-registration form and 30 signed the e-consent. The digital version of the PARCA-R was completed by the parents of 21 of 23 children who reached the appropriate age window. Clinicians and parents found the system easy to use. Only one parent declined permission to integrate data into the National Neonatal Research Database for approved secondary purposes.

**Discussion** This electronic data collection system and associated automated processes enabled efficient systematic capture of data on language and cognitive development in high-risk children, suitable for national delivery at scale.

## INTRODUCTION

The assessment of cognitive and language development in children born very preterm and/or at risk of impaired neurodevelopment following admission to neonatal care

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Though a UK standard of care for at-risk infants admitted for neonatal care, the assessment of language and cognitive development at age 2 years is not systematically undertaken, nor are results available for secondary purposes.

### WHAT THIS STUDY ADDS

⇒ We show that a digital approach for obtaining consent, sending automated notifications and capturing parent-reported data on a child's cognitive and language development at the age of 2 years is acceptable to clinical teams and parents, and feasible for national delivery at scale. Parents also found acceptable the incorporation of results into a national database for approved secondary purposes.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The development of this digital approach to data collection provides an efficient solution to capture national data at scale and reduce the costs of obtaining data on cognitive and language development at the age of 2 years for clinical care, randomised trials, health services research and policy development.

is a UK standard of care. The National Institute for Health and Care Excellence (NICE) recommends that babies born below 30 weeks' gestation, or at 30–36 weeks' gestation with additional risk factors for developmental problems and disorders, should be followed up to 2 years of age.<sup>1–3</sup> These data are also essential for follow-up evaluations of babies who participate in obstetric and neonatal studies, for which neurodevelopmental impairment at 2 years of age is frequently a key outcome.<sup>4</sup> In addition, neurodevelopmental

outcomes comprise components of the core outcomes set for neonatal medicine, which clinicians, parents and researchers consider all clinical trials should record.<sup>5</sup>

In the UK, there is currently no national, systematic approach for assessing and recording the results of assessments of cognitive and language development in children born very preterm and other infants who are at risk of impaired neurodevelopment. Among many challenges are the need to keep in touch with families, the inconvenience of having to attend clinic appointments, the requirement for appropriately trained staff and the costs of follow-up assessments.

The present situation is that many children do not receive these assessments, and some receive separate assessments for clinical and research purposes. Additionally, many neonatal studies lack this important information because of the difficulty in securing funding for long-term follow-up. The lack of a uniform system also results in wide variation in the types of developmental assessments undertaken, making it difficult to harmonise and interpret data at a population level. When funding for research evaluations is available, children and their families often experience the burden of multiple separate assessments for clinical care and research, as there are no systematic processes for sharing data obtained as part of clinical practice for research and vice versa.

The Parent Report of Children's Abilities-Revised (PARCA-R) is a standardised, norm-referenced, parent-completed questionnaire that can be used to assess cognitive and language development at 23–27 months of age and identify children with developmental delay.<sup>6,7</sup> It is recommended by NICE as a clinical tool to assess the development of children born preterm<sup>1–3</sup> and by The International Consortium for Health Outcomes Measurement for assessing development at 2 years of age for all children who were born preterm or hospitalised in the neonatal period.<sup>8</sup> It is also widely used as an outcome measure in observational studies and clinical trials.<sup>9–15</sup>

For follow-up to be effective, parent participation must be high, and the data require secure storage and well-governed processes for access. Here, we describe the development and refinement of a systematic approach to developmental follow-up using a digital version of the parent-completed PARCA-R and processes to incorporate the results into a mature well established, UK Health Research Authority approved national asset, the National Neonatal Research Database (NNRD)<sup>16,17</sup> so that they can be used for approved secondary purposes with parent agreement.

## METHODS

### Aims and setting

The aim of this service improvement study was to develop and test a systematic approach to administering the PARCA-R questionnaire, obtaining parent consent and responses, storing the results in the NNRD and making them available to parents and the child's clinical team.

We involved all west-London National Health Service neonatal units (Chelsea and Westminster; West Middlesex; Queen Charlotte's and Chelsea; St Mary's; Northwick Park; Hillingdon).

### Study design

We developed the study in collaboration with parents; the British Association of Perinatal Medicine; British Association of Neonatal Neurodevelopmental Follow-Up; Bliss, the national charity for babies born preterm or sick; and clinicians from north-west London neonatal units. We held three focus groups to engage and involve parents (five women and one man) and obtain their views during the design of the study.<sup>18</sup>

### Patient recruitment, sites and duration

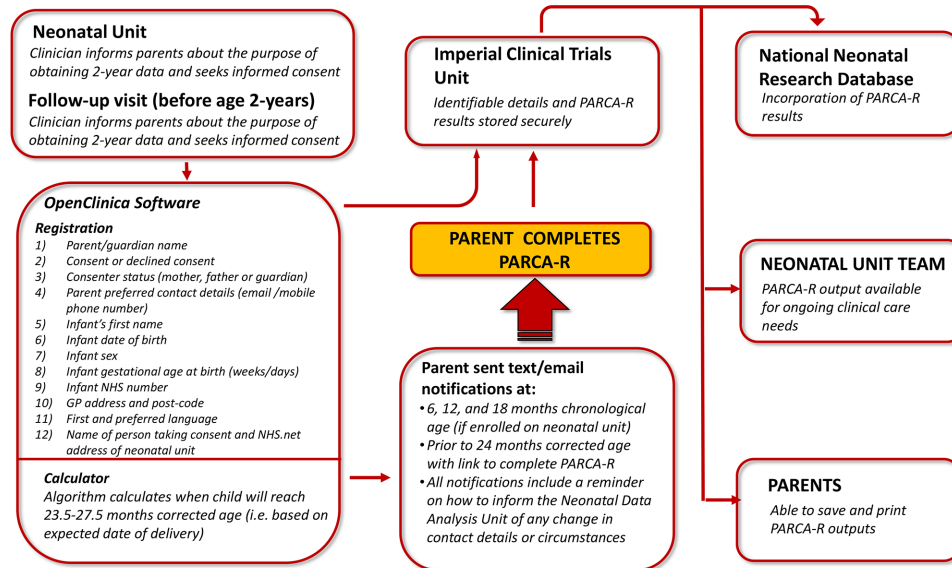
We recruited parents of babies born less than 30<sup>+0</sup> weeks of gestation, either at the time of neonatal unit discharge, or after discharge and prior to the 2-year follow-up outpatient visit. The study had a total duration of 1 year with a recruitment period of 6 months.

### Technology, governance and storage

The Imperial Clinical Trials Unit Clinical Data Systems team, in collaboration with neonatal clinicians, employed standard software (OpenClinica V.4) to develop a digital technology application to enable parents to complete the PARCA-R electronically. Prototype e-forms were refined in-house taking into consideration feedback from clinicians and parents. The OpenClinica application included electronic consent forms completed by parents providing their permission to receive automated reminders and use personal identifiers to link PARCA-R data into the NNRD. In addition to facilitating electronic data capture, the OpenClinica V.4 software can generate reports, study metrics and functions in accordance with Standard Operating Processes. The OpenClinica V.4 platform is compliant with all necessary regulations (21 Code of Federal Regulations Part 11; Good Clinical Practice; General Data Protection Requirement; Health Insurance Portability and Insurance Act Annex 11) and is an all in one, cloud-hosted system, applying zero data loss architecture for failure resilience and recovery to the very last transaction with a 4-week backup data retention period. Personal identifiers were collected to facilitate completion of the questionnaire and reporting of results to parents (figure 1). These were stored securely and separately from all other study data. Data were encrypted at rest and in transit to ensure the highest level of data protection.

### Study processes

At the time of discharge from the neonatal unit, or when approaching the 2-year follow-up clinic visit, a member of the neonatal clinical team approached parents to invite their participation (figure 1). The clinician explained the purpose of the study, provided written information (online supplemental file 1), sought e-consent to participate (online supplemental file 2), registered parent



**Figure 1** Data flows for families enrolled on the neonatal unit or after neonatal unit discharge. PARCA-R, Parent Report of Children's Abilities-Revised. NHS: National Health Service

contact details and completed an e-registration form (online supplemental file 3). Parents who agreed to participate received automated notifications when their child reached 6, 12 and 18 months chronological age. These reminded the parent to inform the Neonatal Data Analysis Unit at Imperial College London where the NNRD is maintained, of any change in contact details or circumstances. When approaching 24-months corrected age (online supplemental file 4), parents were sent an invitation to complete the PARCA-R electronically on a tablet, laptop, desktop computer or mobile phone when their child reached the age of 23.5–27.5 months age corrected for prematurity. On completion of the PARCA-R questionnaire, parents were able to save and print a copy of their child's results (online supplemental file 5). During the registration process, clinicians offered parents a choice to receive notifications by email, by text or both. We randomly allocated parents who selected both methods to receive notifications by either email or email plus text.

Access to personal identifiers was only available to an authorised member of the research team. We used personal identifiers and contact details with parent consent, only for the following purposes: (1) confirm eligibility, (2) contact parents, (3) personalise communications, (4) calculate the child's age, (5) link the PARCA-R score to the infant's NNRD record and (6) send without-obligation notifications about studies and links to information that might be of interest to the parents or importance to the child.

The PARCA-R results were stored pseudonymised with the child's record in the NNRD. In addition, we sent a copy by Secure File Transfer Protocol to a specific NHS.net address so that each neonatal unit participating in this study could incorporate the results into the child's clinical record.

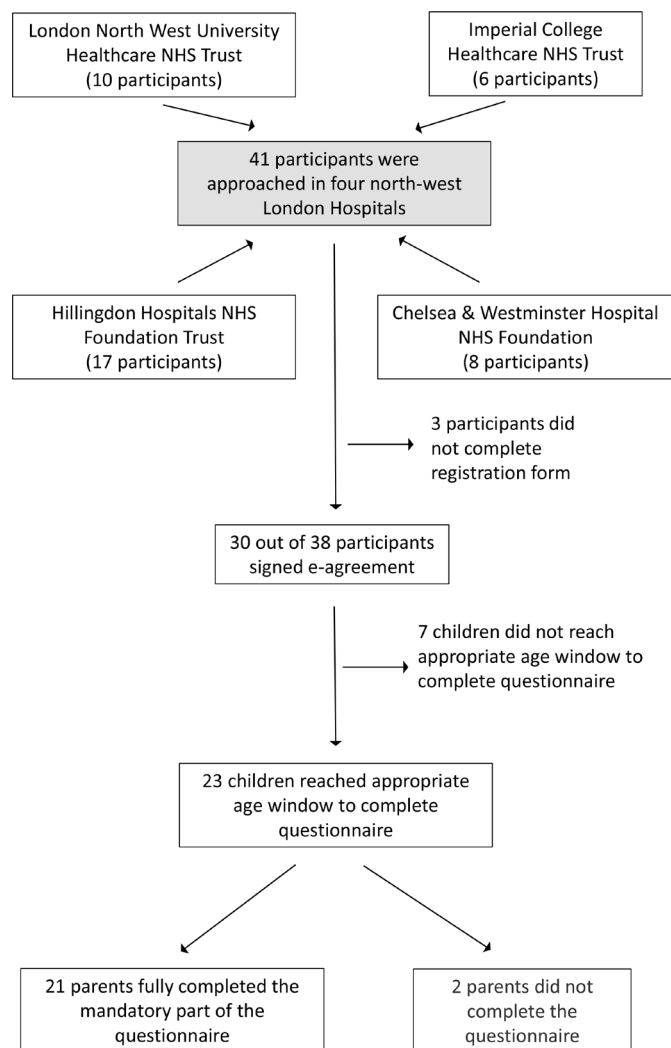
We undertook descriptive analysis to examine consent, uptake and the proportion of missing data for all participants who opened a PARCA-R questionnaire.

## RESULTS

The clinical neonatal teams of north-west London NHS Trusts approached the parents of 41 children: 10 in London North West University Healthcare NHS Trust; 6 in Imperial College Healthcare NHS Trust; 8 in Chelsea & Westminster Hospital NHS Foundation Trust and 17 in Hillingdon Hospitals NHS Foundation Trust. For unknown reasons, 3 out of the 41 parents did not complete the registration form. Out of the 38 participants who completed the registration form, 16 children were girls and 22 were boys. Their gestational ages at birth ranged from 24 to 29 weeks. Twenty-three parents selected English as their first language, 14 selected other languages (Romanian, Turkish, Gujarati, Italian, Arabic, Mandarin, Albanian, Polish and Punjabi) and one was unsure. Of the 38 parents who completed the registration form, 30 completed and 1 started but did not complete the e-agreement (figure 2).

Out of the 41 parents who were invited to participate in the study, 34 were happy to be contacted by text or email and 7 only by text. Of the 34 that agreed to be contacted either way, 19 were randomly allocated to receive notifications by email only and 15 by text and email. Of the ones receiving notifications by email only, 13 (68%) signed the e-consent compared with 11 (73%) in the text plus email group. This difference became more marked when comparing questionnaire completion with 10 (53%) vs 11 (73%) in each group, respectively.

By the end of the study, 30 out of the 38 (79%) participants who signed the registration form went on to sign the e-consent. Of these, only one participant did not agree to



**Figure 2** Numbers of participants. NHS: National Health Service

have their baby's data shared with the clinical team and to be integrated into the NNRD and only two did not agree to be contacted about future studies. Twenty-three of the 30 children reached the appropriate age window for completion of the PARCA-R questionnaire. For these, 21 parents (91%) completed it fully and correctly. Two (9%) were completed incorrectly, one because of erroneous enrolment after the child's second birthday and one because the questionnaire was completed early, before the child was aged 23.5 months, due to a mistake by the clinician when entering the schedule of events.

This digital version of the PARCA-R questionnaire was completed well and it was possible to calculate standardised scores for all 21 children.

Following parent and clinician feedback, we refined the electronic processes. We included a link to the parent information leaflet within the e-agreement form so that parents could access this at any time. We limited the number of characters per notification to reduce the cost of text notifications. We modified standard OpenClinica terminology by replacing the word 'subject' with 'participant' and referred to 'your child', instead of 'this

child'. We resolved technical issues with the display of the PARCA-R scores using iOS in iPhones and a randomisation glitch. We introduced multifactor authentication to access the questionnaire. We modified the NHS number field within the registration form from numeric to text. Finally, we made programming changes to remove the capacity for a clinician to modify the schedule of events inadvertently.

## DISCUSSION

We successfully developed, piloted and refined an electronic system to obtain parent-reported data on cognitive and language development at 2 years of age in children born very preterm. The system was easy to use and acceptable to clinicians and parents. Parents were able to access information about the process and its purpose at any time and were able to complete the questionnaire on a choice of devices. They could choose if they wished to give permission for the questionnaire results to be incorporated into the NNRD, to be made available for other approved uses. They were also able to choose if they wished to receive future information that might be relevant to their child. Importantly, the results of the PARCA-R questionnaire were available to the clinical teams for use in routine developmental follow-up care and parents were able to save and print out a copy of their child's results.

We were able to provide parents with notifications by email and text. Despite a slight increase in cost, this is a helpful option as some parents had no access to email. Overall, completion was higher in the group receiving dual notifications, rather than email alone. A current limitation is that while the PARCA-R questionnaire has been translated into 23 different languages (<https://le.ac.uk/parca-r/translations>), only a small proportion of those translations have been validated to ensure the appropriate selection of words in a culturally appropriate content. This is an important consideration for future development, as 40% of the participants in our study did not consider English their primary language.

The study period overlapped with the COVID-19 pandemic and the alterations to service provision may have affected uptake. We are unable to say whether this was to enhance or decrease uptake.

## CONCLUSIONS

The success of this study suggests that electronic collection of parent-reported data on cognitive and language development for children born very preterm is feasible and suitable for national scale-up. It could improve the clinical care of individual children as well as the efficiency of clinical trials and other studies and reduce the costs of obtaining data on cognitive and language development at the age of 2 years. The incorporation of the results into the NNRD, thereby making these data available to other researchers for approved purposes would mean sparing children and their families the burden of repeated

assessments. It would also enable systematic exploration of outcomes in complete populations of children. Finally, use of a single measure at 2 years of age would obviate the need to harmonise data from multiple developmental tests.

#### Author affiliations

<sup>1</sup>Section of Neonatal Medicine, School of Public Health, Faculty of Medicine, Imperial College London, London, UK

<sup>2</sup>Department of Population Health Sciences, George Davies Centre, University of Leicester, Leicester, UK

<sup>3</sup>Neonatal Medicine, Hillingdon Hospital, Uxbridge, UK

<sup>4</sup>Department of Neonatology, Imperial College Healthcare NHS Trust, London, UK

<sup>5</sup>Neonatal Medicine, Northwick Park Hospital, London, UK

<sup>6</sup>Department of Neonatology, Chelsea and Westminster Hospital NHS Foundation Trust, London, UK

<sup>7</sup>Imperial College Clinical Trials Unit (ICTU), Imperial College London, London, UK

<sup>8</sup>Section of Neonatal Medicine, School of Primary Care and Public Health, Imperial College London, London, UK

<sup>9</sup>British Association of Neonatal Neurodevelopmental Follow-up, Department of Neonatology, King's College Hospital NHS Foundation Trust, London, UK

<sup>10</sup>Nottingham University Hospitals NHS Trust, Nottingham, UK

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**Competing interests** None declared.

**Patient consent for publication** Not applicable.

**Ethics approval** The National Research Ethics Service considered the study a service improvement and hence that approval was not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available on reasonable request.

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#### ORCID iD

Ricardo Ribas <http://orcid.org/0000-0002-8134-0036>

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## **PARENT INFORMATION LEAFLET**

### **Study title**

Systematic electronic capture of parent reported cognitive and language development in children aged two-years (ePARCA-R)

### **The study**

We are carrying out a study to improve services for infants admitted to NHS neonatal units by obtaining information about their development at the age of two-years through an electronic parent questionnaire. The study will initially involve all neonatal units in West London hospitals. The study is supported by the British Association of Perinatal Medicine, British Association of Neonatal and Neurodevelopmental Follow-Up and the charity for preterm and sick babies, Bliss.

We are inviting you to help us with this study. We are approaching you either because your baby is about to be discharged from our neonatal unit, or because your child is attending his or her two-year clinic visit. Please read this, and ask about anything that is unclear.

### **Background**

Assessing development at two years of age is an important part of the care of babies who were born very preterm or sick, as this can help identify those who might benefit from additional support. These assessments are also important in research studies that aim to improve the care we provide to preterm and sick newborn babies.

### **The current situation**

There is currently no national, systematic approach for assessing the development of all two-year old children who received neonatal care. At present, some children receive tests or their parents are asked to complete questionnaires, but not all.

A further difficulty is that if an assessment is done, there are no processes for sharing this information securely with other health professionals or authorised people. Without the ability to share such information safely, families are often called upon to complete multiple assessments by health professionals and researchers. This is burdensome to families, inefficient and a waste of resources.

### **Our proposed approach**

The National Institute of Health and Clinical Excellence (NICE) has recommended the use of the PARCA-R questionnaire to assess a child's thinking skills and language development when they are 2 years of age, so that support can be provided if needed. The PARCA-R questionnaire is completed by parents. It is quick and easy to do, and is used by health professionals and researchers throughout the world.

To try and solve the problem that there is currently no national, systematic approach for assessing the development of all two-year old children who received neonatal care, a team at the Neonatal Data Analysis Unit at Chelsea and Westminster Hospital/Imperial College London have developed a new process to enable parents to complete the PARCA-R securely online, on a computer, mobile phone or other device, and to store the results securely so that they can be shared with other authorised users, including your child's NHS team.

We are inviting you to participate in a study to help test how well this new process works.

**What will this mean for me and my child?**

With your permission we will share your contact details and your infant's NHS number/date of birth with the Neonatal Data Analysis Unit at Chelsea and Westminster Hospital/Imperial College London for the specified purposes listed below; we will record your decision electronically. The Neonatal Data Analysis Unit will only use your contact details for the following purposes and will not release them to any person or organisation.

**If your baby is on the neonatal unit, the Neonatal Data Analysis Unit will send you:**

- Notifications by email when your child is aged 6 months, 12 months, and 18 months from birth, by text or email, to remind you to inform them of any change in your contact details or circumstances
- Without-obligation notifications about studies and links to information that might be of interest to you or of importance to your child
- When your child is approaching the age of two-years corrected for prematurity, a notification and a link to authenticate your identity and complete the ePARCA-R; you will also be able to save and print a copy of the ePARCA-R for yourself

**If you are the parent of a child who will be due to attend a two-year follow-up clinic, the Neonatal Data Analysis Unit will send you:**

- Without-obligation notifications about studies and links to information that might be of interest to you or of importance to your child
- A notification and a link to authenticate your identity and complete the ePARCA-R; you will also be able to save and print a copy of the ePARCA-R for yourself

**What will happen to the ePARCA-R questionnaire result?**

- We will store a copy of the results with your child's record in the National Neonatal Research Database at the Neonatal Data Analysis Unit where it will be available anonymously for authorised uses. The National Neonatal Research Database supports a large number of studies to improve the care of babies admitted to neonatal units. You should have received information about the National Neonatal Research Database from your neonatal unit, and you can also find a copy [here](#).
- We will also send a copy to be stored with your child's west London NHS Whole Systems Integrated Care Record so that this is available to your child's NHS healthcare providers

- You will be able to save or print a copy of the completed questionnaire and your child's results for yourself

**Will my details and my child's details be kept confidential?**

Your details and your child's will be stored confidentially. Only your child's NHS healthcare providers and authorised members of the research team will be able to access identifiable data

**What if I change my mind?**

You are free to change your mind and withdraw your permission for the Neonatal Data Analysis Unit to store your contact details and infant NHS number/date of birth at any time without having to give a reason. If you notify the Neonatal Data Analysis Unit that you have withdrawn your consent, your details and your infant's details will be deleted. If you have already submitted the ePARCA-R this will not be deleted but will be stored anonymously.

**Who is organising and funding this study?**

This study is funded and organised by Imperial College London. You can find out more about how Imperial College London uses personally-identifiable information to conduct research to improve health, care and services in the Neonatal Data Analysis Unit [Privacy Notice](#).

**Thank you for reading this information sheet****Contacts for further information**

**Chief Investigator:** Professor Neena Modi, Imperial College London ([n.modi@imperial.ac.uk](mailto:n.modi@imperial.ac.uk))

**West London Hospital Leads:**

- Hillingdon Hospitals NHS Foundation Trust: Dr Elizabeth Lek, Consultant Neonatologist ([elizabeth.lek@nhs.net](mailto:elizabeth.lek@nhs.net))
- Imperial NHS Trust (Queen Charlotte's and Chelsea Hospital; St Mary's Hospital): Dr Sunit Godambe, Consultant Neonatologist ([sunit.godambe@nhs.net](mailto:sunit.godambe@nhs.net))
- Northwick Park Hospital: Dr Edit Fukari-Irvine, Consultant Neonatologist ([edit.fukari-irvine@nhs.net](mailto:edit.fukari-irvine@nhs.net))
- Chelsea and Westminster NHS Foundation Trust: Dr Nora Tusor Consultant Neonatologist ([nora.tusor@nhs.net](mailto:nora.tusor@nhs.net)) and Dr Enitan Ogundipe Consultant Neonatologist ([enitan.ogundipe@nhs.net](mailto:enitan.ogundipe@nhs.net))
- West Middlesex Hospital: Dr Elizabeth Eyre, Consultant Neonatologist ([eeyre@nhs.net](mailto:eeyre@nhs.net))



## 1-111: ELECTRONIC AGREEMENT FORM



**TITLE:** Systematic electronic capture of parent reported cognitive and language development in children aged two-years (ePARCA-R)

**Chief Clinician:** Professor Neena Modi

**Child's name:**

\_\_\_\_\_

**Parent Information Sheet for the ePARCA-R service evaluation study:** [https://www.imperial.ac.uk/neonatal\\_data\\_analysis\\_unit/service\\_improvement\\_studies/eparca-r/parent\\_information/](https://www.imperial.ac.uk/neonatal_data_analysis_unit/service_improvement_studies/eparca-r/parent_information/)

\* Please tick the boxes below to agree

- 1) I confirm that I have read the Parent Information Sheet for the ePARCA-R service evaluation study; I have had the opportunity to consider the information, ask questions and have these answered
- 2) I understand that my child's participation is voluntary and that I am free to withdraw at any time without giving any reason, without my child's medical care or legal rights being affected
- 3) I understand that sections of any of my child's medical notes may be looked at by responsible individuals from Imperial College London or regulatory authorities where it is relevant to my child taking part in this study
- 4) I give permission for my child's ePARCA-R results to be entered into my child's NHS records
- 5) I give consent for information collected about my child in this study to be used to support approved research in the future, including studies outside the European Economic Area; I understand that my child will not be identified or named in this or any future research
- 6) I give permission for my child's ePARCA-R results to be entered into my child's record in the National Neonatal Research Database where it may be used to support other approved research in future; I understand that my child will not be identified or named in this or any future research
- 7) I agree to being contacted in the future about future studies of interest to my child
- 8) I agree to my child taking part in this study

Name of Parent/Guardian/Legal Representative

\_\_\_\_\_

Signature

Date

yyyy-mm-dd \_\_\_\_\_

Name of person explaining the ePARCA-R process (enrolling participants)

Please type 'Other' if the name is not in the list and specify the name in the box that appears below.

\_\_\_\_\_

Please specify

\_\_\_\_\_

Signature






Date

yyyy-mm-dd \_\_\_\_\_

**1-111: Registration Form**

Parent/Guardian Surname *	Parent/Guardian First Name *
Relationship to Infant * <input type="radio"/> Mother <input type="radio"/> Father <input type="radio"/> Legal Guardian	
Infant First Name *	
Infant Date of Birth * yyyy-mm-dd	
Infant Sex * <input type="radio"/> Boy <input type="radio"/> Girl	
Family's First Language *	
Family's Preferred Language *	
Select Infant's Gestational Age at Birth * <i>Weeks</i> <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> 11 <input type="radio"/> 12 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> 15 <input type="radio"/> 16 <input type="radio"/> 17 <input type="radio"/> 18 <input type="radio"/> 19 <input type="radio"/> 20 <input type="radio"/> 21 <input type="radio"/> 22 <input type="radio"/> 23 <input type="radio"/> 24 <input type="radio"/> 25 <input type="radio"/> 26 <input type="radio"/> 27 <input type="radio"/> 28 <input type="radio"/> 29 <input type="radio"/> 30	And days: * <i>Days</i> <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6
Infant NHS Number *	
Name of person explaining the ePARCA-R process (enrolling participants) *	
Hospital *	
GP Address *	
GP Postcode *	

## Thank you for registering for the ePARCA-R study (6-Month Notification)

**D** donotreply@openclinica.io      ...

Wed 07/07/2021 08:00  
To:






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\*\*\*\*\*

Dear Child001  
Thanks for joining ePARCA-R! Click <https://www.imperial.ac.uk/neonatal-data-analysis-unit/service-improvement-studies/eparca-r-/parent-information/> to review information and notify us of changes in your contact details  
The ePARCA-R team

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## Thank you for registering for the ePARCA-R study (12-Month Notification)

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Dear Child001  
Thanks for joining ePARCA-R! Click <https://www.imperial.ac.uk/neonatal-data-analysis-unit/service-improvement-studies/eparca-r-/parent-information/> to review information and notify us of changes in your contact details  
The ePARCA-R team

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## Thank you for registering for the ePARCA-R study (18-Month Notification)

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\*\*\*\*\*

Dear Child003  
Thanks for joining ePARCA-R! Click <https://www.imperial.ac.uk/neonatal-data-analysis-unit/service-improvement-studies/eparca-r-/parent-information/> to review information and notify us of changes in your contact details  
The ePARCA-R team

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## Please remember to complete the ePARCA-R questionnaire

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<https://spam.ic.ac.uk/SpamConsole/Senders.aspx> to disable email stamping for this address.  
\*\*\*\*\*

Dear Child006  
Last reminder! There's only 2 weeks left to fill in the ePARCA-R questionnaire  
<https://eparcartest.mytrial.me> for accurate results.  
Access Code: dE2PE4Uff  
The ePARCA-R team

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You're in review-only mode.



## 4-005: ePARCA-R Questionnaire

### Date of assessment

To obtain ePARCA-R standard scores, enter the date of ePARCA-R assessment. Child's age or corrected age (if the child was born preterm) will be calculated based on the entered date of assessment. Percentiles are only calculated for children aged between 23 months 16 days and 27 months 15 days at the time of assessment.

yyyy-mm-dd

Your child has a non-verbal cognitive scale score of **NaN**, and a standard score of . This is on the percentile. This means that % of children in the general population have scores equal to or less than your child's score.

Your child has a language scale score of **0**, and a standard score of . This is on the percentile. This means that % of children in the general population have scores equal to or less than your child's score.

**Please Note: This will be your last chance to print a copy of your results. You can do this by accessing your ePARCA-R Questionnaire on a computer/laptop.**

You're in review-only mode.

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