The SMARTIE Evaluation: SMART4NIPE Integrating Evidence – A Service Evaluation.

A service evaluation using routinely collected data, using the national Smart4NIPE data collection tool, to report the frequency, variation in treatment and outcomes of Developmental Dysplasia of the Hip (DDH) in infants using a nationally agreed core measurement set.

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Service Evaluation Team

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Clinical Queries

Clinical queries should be directed to Professor Daniel Perry who will direct the query to the appropriate person.

Funder

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Executive Summary

1 in 1000 babies are born with a hip(s) completely out of the socket, and many more have minor hip problems. All UK newborn babies are part of a national hip screening programme, to identify dislocated hips, with an examination occurring around birth and at 6-8 weeks. However, it is recognised that the programme has major flaws, with two-thirds of dislocated hips missed by screening. Across Europe and the world, doctors use different ways to 'screen' the hips of infants. In many parts of Europe every baby has an ultrasound scan of the hips, whereas in other parts, such as the UK, babies receive an examination without an ultrasound scan. Other countries, such as the US, have no mandated screening tool, arguing that there is insufficient evidence that screening for dislocated hips is beneficial to children and their families.

Even when a dislocated hip is diagnosed, through screening or opportunistic identification, there is often disagreement on when to start treatment, how to treat the hip and when to stop treatment. In fact, doctors even disagree on making the diagnosis, i.e. when to call a 'dislocated hip' a 'dislocated hip'. A UK 'core measurement set' has now been agreed upon to enable clinicians to uniformly describe the diagnosis and severity of DDH. The Newborn Infant and Physical Examination (NIPE) screening programme for England has recently begun to record details of each infant screening episode on a national database – called Smart4NIPE. NIPE have embedded the core measurement set into the Smart4NIPE database, enabling high-quality audit and service evaluation.

Work is now needed to describe the disease characteristics, based on the embedded core measurement set, to explore the use of screening and treatment pathways, and the influence on outcomes. Understanding current NHS pathways will support improvements in the quality of the national DDH screening service.

GLOSSARY OF ABBREVIATIONS

NIHR	National Institute for Health and Care Research
DDH	Developmental Dysplasia of the Hip
EATC	Experimental Arthritis Treatment Centre
NIPE	Newborn and Infant Physical Examination
NSC	National Screening Committee

KEYWORDS

Hip Dysplasia, Dislocated Hip, Screening, Osteoarthritis

Title	**The SMARTIE Evaluation: SMART4NIPE Integrating Evidence – A Service Evaluation.** A service evaluation using routinely collected data, using the national Smart4NIPE data collection tool, to report the frequency, variation in treatment and outcomes of Developmental Dysplasia of the Hip (DDH) in infants using a nationally agreed core measurement set.
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Funder	National Institute of Health and Care Research, Research Professorship
Clinical Evaluation Group	Liverpool Orthopaedic and Trauma Trials Group Institute in the Park. University of Liverpool. L12 2AP
Brief title (acronym)	**The SMARTIE Evaluation: SMART4NIPE Integrating Evidence – A Service Evaluation.**
Central contact	Lucy Cooper/Richard Kirk Liverpool Orthopaedic and Trauma Trials Group Institute in the Park. University of Liverpool. L12 2AP
Countries of recruitment	UK
Focus of evaluation	To report the frequency, variation in treatment and outcomes of Developmental Dysplasia of the Hip (DDH) in infants using a nationally agreed core measurement set.
Health condition	Developmental Dysplasia of the Hip (DDH)
Key eligibility criteria **Inclusion Criteria:** **Exclusion Criteria:**	Neonates under 3 months old screened as part of the national screening program. Nil
Evaluation design	Service evaluation using routinely collected data

Population	Children following the introduction of the Hip Core Measurement Set to the Smart4NIPE database (2024 onwards).
Planned period	18 months
Primary objective	To report the frequency of Developmental Dysplasia of the Hip recorded within the Smart4NIPE record.
Secondary objectives	- Report the incidence of DDH in England identified through the screening program - Report the variation in treatment for DDH - Rerport the routinely collected outcomes of DDH, stratified by patient and treatment factors.

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1. INTRODUCTION

1.1 BACKGROUND

Developmental Dysplasia of the Hip (DDH) is a spectrum of disease. 1 in 1000 newborns have a completely dislocated hip, and 2-3% are diagnosed with some degree of hip dysplasia[1] DDH is associated with premature osteoarthritis and is the cause of 10% of all hip replacements, and a third of replacements in those under 60 years old[2]. In the UK around 1,200 total hip replacements per year occur as a result of DDH, which is more than that for all inflammatory arthropathies combined.

Early diagnosis is crucial to minimise the need for surgery in childhood and maximise long-term outcomes. In the early infant period DDH can usually be treated with a removable splint (typically a Pavlik harness) which is worn for a period of a few weeks, and generally results in a hip which is structurally and functionally normal. Hips that are diagnosed in children older than 6 months of age usually require a spica cast (plaster trousers) for a period of up to six months. In addition to the spica cast, infants diagnosed after one year of age require surgery to divide tendons and surgically relocate the hip. Those diagnosed at later times require increasingly complex surgery to divide tendons, surgically relocate the hip or to break bones and reposition the bones around the hip to aid the development of the socket. Despite more complex surgery, hips diagnosed at later time periods have poorer functional outcomes with more long-term disability due to early degenerative joint disease. Diagnosis and treatment early in the life of the infant appears key.

The UK uses a nationwide selective ultrasound screening programme for DDH[3]. Screening is carried out as part of the statutory Newborn and Infant Physical Examination (NIPE) screening programme. All babies are screened within 72 hours of life, and again at 6-8 weeks. Screening is usually carried out by midwives, paediatricians and general practitioners. Hip screening begins with a series of questions to identify risk factors for disease (i.e. third trimester breech position, first degree relative affected by DDH). Additionally, a mandatory clinical examination is performed on all babies, which includes an examination of hip abduction, limb length and special tests known as the 'Ortolani' and 'Barlow' manoeuvres. If any aspects of the screening examination are abnormal, or if the child has significant risk factors, then they are referred for ultrasound screening.

Clinical examination of the hips requires skill and experience to perform[4]. Ortolani and Barlow manoeuvres involve moving the child's legs into predefined positions, and the examiner feeling the hip to identify the hip dislocating and 'clunking' back into position. The experience of any single examiner in identifying abnormalities of the hips is low, as the diagnosis of DDH is rare. The National Screening Committee have identified that it is very difficult to adequately train individuals, or to monitor standards relating to these tests. Overall, the national screening committee have estimated that the current screening regimen misses up to two thirds of true cases of DDH[5].

1.2 RATIONALE FOR CURRENT SERVICE EVALUATION

It is widely recognised that there are significant problems with the current screening programme. Indeed, a recent observational study using the Clinical Practice Research Database (CPRD) demonstrated that rates of surgery for DDH appear unchanged now, as they did prior to the introduction of screening in 1980 [6]. A major factor is that clinical examination of the hips requires skill and experience to perform, yet the experience of any single examiner is low as the diagnosis is very rare. Scotland have moved toward a system of 'expert examiners', which is believed to have improved detection [7]. However, it has been shown that even a group of expert surgeons, specialising in childhood hip disease, find the examination challenging [8]. A further failure, is the 'risk factors' used to trigger an ultrasound are uncertain and debated [9-12]. Furthermore, if a child is referred for ultrasound, there is no agreement of the technique used for the scan [13], with some users performing dynamic scans to 'dislocate' the hip under vision, and others using a 'static' scan to characterise the hip at rest.

There is a strong desire amongst the community of children's orthopaedic surgeons and associated allied health professionals, patients and the public to strengthen the evidence regarding screening for and treatment of DDH. The James Lind Priorities for Planned Surgery to the Lower Limbs in Children and The British Society for Children's Orthopaedic Surgery (BSCOS) both highlighted the screening and treatment for DDH is a key priority for audit, evaluation and research [14,15].

Capitalising on Routine Data Collection

There has been a national (NHS-England) roll-out of a mandatory national screening information system (Smart4NIPE) for recording the pathway of children within the NIPE screening programme. This forms part of the national infant screening reporting mechanism and acts as a failsafe to ensure babies do not miss screening opportunities. A national network of dedicated nurses and midwives perform periodic audits, to verify the completeness of the data. The data collected beyond the 'primary screen' (i.e. the initial infant examination) is currently largely 'process data', concerning the attendance for screening visits (i.e. date of an ultrasound scans). In the example of infant hips, in addition to the date of the scan, there is a notional record of whether the scan was 'normal' or 'abnormal'. However, there is significant disagreement amongst clinicians about what constitutes 'normal' and 'abnormal', therefore the data collected is of little value.

The Core Measurement Set & UK Consensus

The British Society for Children's Orthopaedic Surgery (BSCOS) led a Delphi consensus exercise amongst its members to agree a pathway for the treatment of infants diagnosed with DDH before 3 months old [16]. BSCOS members agreed a 'core measurement set' for ultrasound examination, which is the minimum dataset that must always be recorded, which can be used to define whether the hip is 'normal' or 'abnormal'. The BSCOS members agreed that the 'core measurement set' should be collected on national database, alongside details of any treatments to facilitate evaluation, audit and research.

The Core Measurement Set for the diagnosis of DDH includes three questions:

- Is the hip centered?
- What is the alpha angle?
- Is the hip sonographically unstable?

BSCOS also sought agreement on pathways for the treatment of DDH, based on disease severity and the time of diagnosis. Whilst there were many areas of agreement, there were also many areas of controversy.

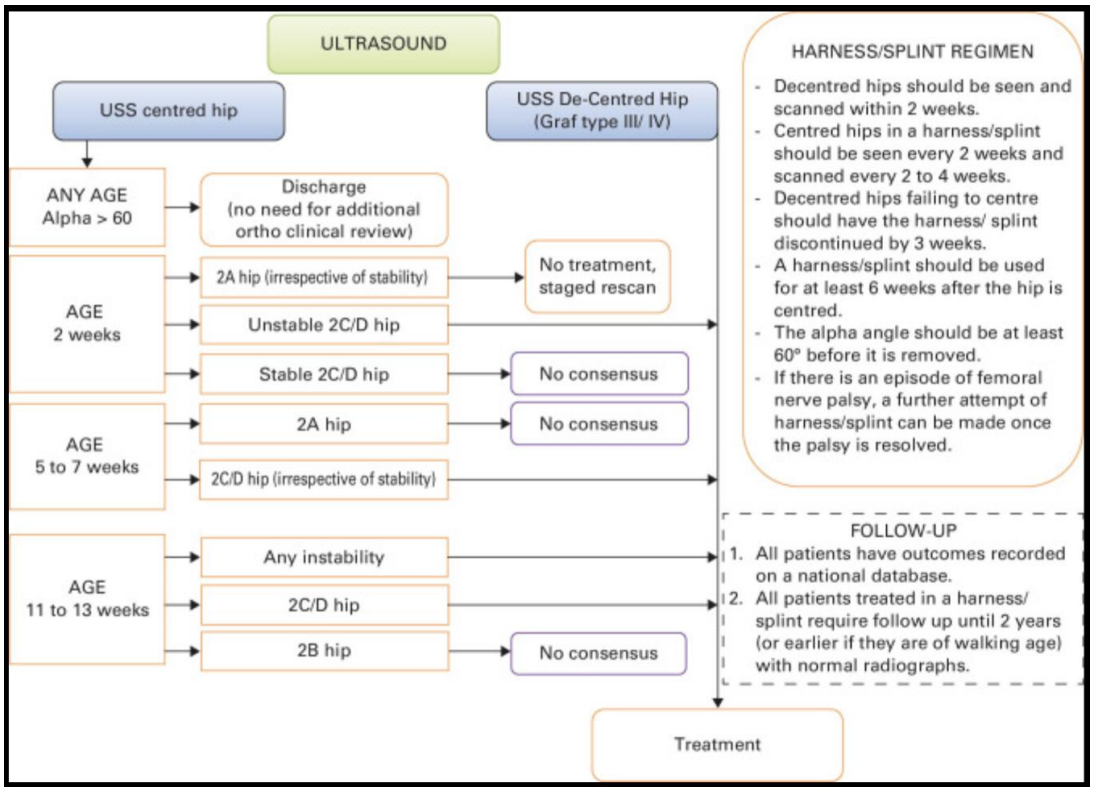


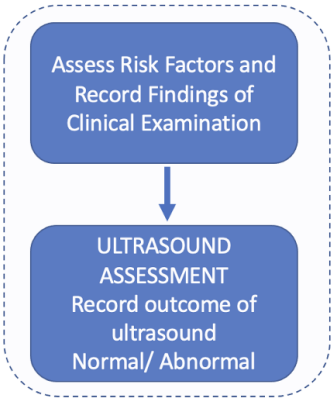
Figure - BSCOS Consensus Pathway for DDH Treatment

Treatment pathways caused considerable disagreement, which was largely related to the type of splint, the timing of splint application and the timing of splint removal. The disagreement is propagated through a lack of evidence, which was highlighted by a recent Cochrane review in this area [17]. The low quality of evidence, coupled with significant treatment variation, has led to calls for UK-wide consensus in treatment pathways[13].

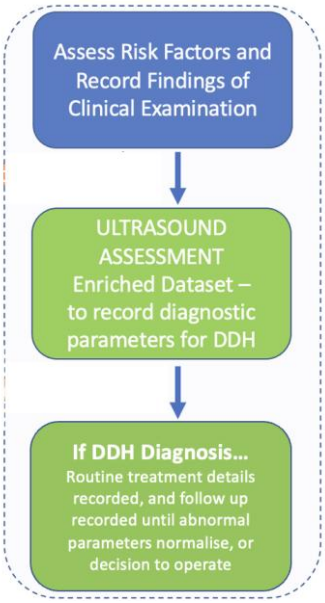
Enriching the NIPE Smart Database

In 2023 NHS England agreed to embed the BSCOS 'core measurement set' for DDH diagnosis, and simple treatment characteristics in the Smart4NIPE Dataset, which was implemented in 2024. This has enabled the data collection tool to move beyond a crude assessment of normal vs. abnormal, to a tool that clinicians could better describe disease severity and outcomes.

Previous NIPE Pathway



Enriched NIPE Pathway Modification



Prof Anne Mackie (Director of Screening, PHE) and Prof Simon Kenny (National Clinical Director for Children) and the operational leadership within NHSE were instrumental in supporting the changes to the programme, with the view to gaining greater insights into the current screening and treatment pathways for DDH. The changes implemented, and this evaluation, align well with the NHS 10 Year Health Plan (Fit for the Future, July 2025), which prioritises the shift from sickness to prevention and the use of digital innovation to improve screening programmes.

2. AIMS/ OBJECTIVES

The aim of the evaluation is to:

- Report the incidence of DDH in England identified through the NIPE screening programme, using varying diagnostic thresholds.
- Report the frequency of the use of ultrasound examination in the DDH screening pathway in England.
- Report the frequency of True Positives screens and False Positive screens using varying ultrasound diagnostic thresholds.
- Report variations in the treatment pathways for DDH.

3. SERVICE EVALUATION DESIGN

Data is routinely collected from all English maternity units and their associated paediatric orthopaedic referral centres as part of the NHS-England screening failsafe mechanism. We will conduct a national service evaluation using data collected after the introduction of the core measurement set into Smart4NIPE database.

We will collect anonymised data detailing the following;

Primary Screening Visit

Age of the patient at primary screening (Days).

Sex

Risk Factors

Details of examination

Subsequent Screening Visit

Age of the patient at screening visit

Core Measurement Set Data

Visit outcome

Ongoing Treatment Details

Subsequent Treatment Visit

Age of the patient at screening visit

Core Measurement Set

Visit Outcome

Ongoing Treatment Details

4. PARTICIPANT ENTRY

4.1 INCLUSION CRITERIA

Neonates enrolled into the English Newborn and Infant Physical Examination program.

4.2 EXCLUSION CRITERIA

Nil

5. STATISTICS AND ANALYSIS

Outcomes recorded within the core measurement set will be described using summary statistics, stratified by patient characteristics and treatment pathway. For binary outcomes (e.g. centred vs. de-centred hip) proportions will be reported by subgroup; for continuous outcomes (e.g. alpha angle) means and distributions will be reported by subgroup. Where regression modelling is used, it serves to account for case mix when describing variation across the population - consistent with established national clinical evaluations/ audits such as the National Joint Registry and the National Hip Fracture Database. No hypothesis is tested and no causal inference is drawn.

A formal analysis plan, will be developed prior to analysis. This will be agreed with the Evaluation Steering Committee prior to implementation. The analysis plan will be overseen by the lead statistician for the evaluation, Richard Jackson (University of Liverpool).

6. EVALUATION MANAGEMENT

The day-to-day management of the service evaluation will be coordinated through the Alder Hey SECTOR research group.

7. END OF EVALUATION

The end of the service evaluation is defined as when all deliverables, as previously set out in the protocol, have been achieved.

8. ARCHIVING

Data and all appropriate documentation should be stored for a minimum of 10 years after the completion of the service evaluation, including the follow-up period, unless otherwise directed by the

funder/sponsor/regulatory bodies.

9. TRANSPARENCY AND DATA PROTECTION

This service evaluation uses pseudo anonymised data extracted from the Smart4NIPE national screening database by NHS England prior to transfer to the evaluation team. NHS England replaces all direct identifiers with a unique participant reference code before transfer; the key linking that code to an individual's identity is held solely by NHS England and is not shared with the evaluation team. Although the evaluation team cannot re-identify data subjects from the dataset received, pseudo anonymised data remains personal data under UK GDPR, and the University of Liverpool fulfils its data controller obligations accordingly.

No individually identifiable data is accessed, processed, or retained by the evaluation team at any point.

Purpose of Processing

The University of Liverpool processes the pseudo anonymised dataset (13.2 core measurement set) exclusively for the purposes of this service evaluation, namely:

- To report the frequency and incidence of Developmental Dysplasia of the Hip (DDH) identified through the NIPE screening programme in England
- To report the frequency of ultrasound examination within the DDH screening pathway
- To report variation in treatment pathways for DDH
- To report routinely collected outcomes of DDH, stratified by patient and treatment factors, using the nationally agreed core measurement set embedded in Smart4NIPE

The data will not be used for any purpose incompatible with the service evaluation objectives set out in this protocol and will not be used for commercial purposes.

Legal Basis for Processing

The legal basis for processing is Article 6(1)(e) of UK GDPR — processing necessary for the performance of a task carried out in the public interest — and Article 9(2)(h) — processing necessary for the purposes of preventive medicine and the provision and management of health care systems and services. Processing is consistent with NHS England's statutory responsibilities under the NHS Act 2006 to commission, monitor and quality assure national screening programmes, and with the University of Liverpool's public research function.

Data Controller and Contact Details

The University of Liverpool acts as Data Controller for the analytical phase of this evaluation, operating under a formal Data Sharing Agreement with NHS England. The University is registered with the Information Commissioner's Office (ICO) under registration number Z6390975.

Data Protection Officer: Gaige Corvo legal@liverpool.ac.uk

Evaluation Lead / Principal Point of Contact: Professor Daniel Perry, NIHR Research Professor Liverpool Orthopaedic and Trauma Trials Group, University of Liverpool danperry@liverpool.ac.uk

Data Security

Pseudo anonymised data is held and processed exclusively on University of Liverpool-approved, password-protected systems. Access is restricted to named, trained members of the evaluation team only. University network drives and University-approved platforms (including Microsoft SharePoint where applicable) are used in accordance with the University's Information Security Policy. Storage of data outside University-approved systems requires prior approval from the University's Computing Services Department.

Data Retention

Data will be retained for a minimum of 10 years following completion of the evaluation, in accordance with the NHS Records Management Code of Practice and the University of Liverpool's Data Management Policy. At the end of the retention period, data will be securely deleted or destroyed in accordance with University records management procedures.

Rights of Data Subjects and How to Exercise Them

Data subjects retain the following rights under UK GDPR:

Data subjects have the following rights under the UK General Data Protection Regulation (UK GDPR):

Right of Access (Article 15) You have the right to request a copy of the personal data held about you and information about how it is being used. To exercise this right, contact the Evaluation Lead (details below). The evaluation team will coordinate with NHS England where re-identification is necessary to locate and retrieve the relevant record.

Right to Rectification (Article 16) You have the right to request correction of inaccurate or incomplete personal data held about you. As data originates from the Smart4NIPE national screening database, correction requests will be coordinated with NHS England. Please contact the Evaluation Lead in the first instance.

Right to Erasure (Article 17) You have the right to request deletion of your personal data. Please note that where data has already been incorporated into aggregated statistical outputs or published findings, full erasure may not be possible without compromising the integrity of the evaluation. Where this limitation applies, you will be informed in writing.

Right to Restriction of Processing (Article 18) You have the right to request that processing of your personal data is restricted — for example, whilst a concern about accuracy or the lawfulness of processing is under review. During any period of restriction, data will be retained but not actively processed.

Right to Object (Article 21) You have the right to object to the processing of your personal data where processing is carried out on the basis of public task (Article 6(1)(e) UK GDPR). Objections will be considered and a written response provided within one calendar month. Processing will cease unless compelling legitimate grounds for continued processing can be demonstrated that override your interests, rights and freedoms.

Right to Lodge a Complaint (Article 77) You have the right to lodge a complaint with the Information Commissioner's Office (ICO) at any time if you consider that the processing of your personal data is unlawful or does not comply with UK GDPR. We would welcome the opportunity to address any concern directly before an ICO referral is made.

How to Exercise Your Rights

All requests and enquiries relating to the exercise of data subject rights should be directed to:

Evaluation Lead Professor Daniel Perry, NIHR Research Professor, Liverpool Orthopaedic and Trauma Trials Group, University of Liverpool danperry@liverpool.ac.uk

Requests will be acknowledged within five working days and responded to within one calendar month of receipt, in accordance with UK GDPR requirements. Where a request is complex or numerous requests have been received, this period may be extended by a further two months; you will be informed of any extension within the initial one-month period.

If you are dissatisfied with the response received, you may escalate your concern to:

Data Protection Officer, University of Liverpool - Gaige Corvo legal@liverpool.ac.uk

Information Commissioner's Office (ICO) www.ico.org.uk Telephone: 0303 123 1113

10. PUBLICATION POLICY

Patients and the Public

Material for dissemination will be developed in conjunction with the *patient panel*, the NIHR CRN: Children 'Young Peoples Advisory Group' and STEPS Worldwide, a patient charity represented on the National Screening Committee DDH working group, and who have contributed to the development of this service evaluation.

STEPS have agreed to communicate the outcomes of the work via their newsletter, website and information packages. For the wider public it is planned that the INVOLVE national advisory group will be an important liaison throughout, with dissemination adhering to the 'make it clear' guidance.

Specialists & Generalists:

On completion of the evaluation, results will be formally presented to BSCOS and the British Orthopaedic Association (BOA). A report will be written for the BSCOS committee to inform the national GIRFT (Getting it Right First Time) report. It will seek to target the both the specialist audience, and the generalist.

Policy makers:

Cochrane have produced a review of screening for DDH, recommending further high-quality audit, evaluation and research. If successful, this evaluation is likely to inform future guidelines produced by the National Screening Committee, and may inform to the development of research to improve care.

Patient Involvement

Families were integral to the James Lind Priorities for Planned Surgery to the Lower Limbs in Children, which highlighted the screening and treatment for DDH as a priority for future audit and research [14,15]. Following this, Emma Morely worked alongside us, as a parent co-investigator on a Cochrane review of DDH treatment, to ensure that "the things important to families were not forgotten". Emma has been integral to developing our evaluation proposal.

We have held workshops with affected families, had discussions with the patient charity and gained the support and buy-in from 159 families affected by DDH. Families have shared their experience and stories of DDH screening treatment, and the majority have also committed to help our broader program of work related to DDH proposal, as it evolves.

From families, we have gained particular appreciation of the challenges that 'illness' has in the early infant period. Whilst a hip brace for DDH may be perceived a simple treatment, the inconvenience, burden, cost and additional worry that this brings to new families is significant. Furthermore, families frequently express the frustration and confusion that treatment variation, with the resulting uncertainty that this brings; with social media groups adding to the anxiety by parading the differences in treatment from hospital-to-hospital.

With the families helping to develop this proposal, I have formed a parent oversight group, and have two parents engaged as parent co-investigators on the management team (Emma Morley and Emma Herridge). Lordena Guetg-Wyatt (STEPS Charity) has agreed to provide oversight to the evaluation.

We will also work with the NIHR Young Persons Advisory Group and the Alder Hey Parent and Carers Forum to ensure that I follow best practice when engaging parents.

Ultimately, we hope that this evaluation is a partnership with families, and we are keen to promote parents as co-investigators and co-authors on the outputs

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13.2 Core Measurement Set

Baseline (Universal Examination) - physical screening	
Breech	
Family History	
Other risk factors	
Details of physical examination (select one)	
Normal/ Stable	
Dislocatable (in position at rest, but able to dislocate)	
Dislocated (dislocated at rest)	
Dislocated reducible hip	
Click only	
Baseline (Universal Examination) - physical screening	
Breech	
Family History	
Other risk factors	
Ultrasound Visit 1	
Date of visit	[Today button and date box]
RIGHT HIP	
Is the hip centred?	Y/N (select one)
[If Yes] What is the alpha angle?	(Range 30 - 90)
[If Yes] Is the hip unstable on dynamic ultrasound?	(Yes/No/ Not done (select one)).
LEFT HIP	
Is the hip centred?	Y/N (select one)
[If Yes] What is the alpha angle?	(Range 30 - 90)
[If Yes] Is the hip unstable on dynamic ultrasound?	(Yes/No/ Not done (select one)).
Plan (select one)	
- Follow-up Ultrasound	
- No further ultrasounds (select one)	
- Discharge – normal hip.	
- Planning surgery for closed/open reduction	
- Other	
[If follow-up ultrasound] When is the scan – X weeks	(range 1 - 8 weeks).
[If follow-up ultrasound] Have you started treatment today?	Y/N (select one)).
[If Yes to started treatment] What is the treatment? (select one)	
• Observation • Abduction device (select one) ▪ Pavlik Harness ▪ Fixed Abduction Harness ▪ Other.	
Visit 2 and subsequent (as above)	

Date of scan	[Today button and date box]
[If selected Abduction Device at last visit]. Were there any complications related to the harness since the last visit (select one) YES/NO	
If Yes (select all that apply and ask which side RIGHT/ LEFT)	
Femoral Nerve Palsy	
Skin Problems	
other	
RIGHT HIP	
Is the hip centred?	Y/N (select one)
[If Yes] What is the alpha angle?	(Range 30 - 90)
[If Yes] Is the hip unstable on dynamic ultrasound?	? (Yes/No/ Not done (select one)).
Plan (select one)	
- Follow-up Ultrasound	
- No further ultrasounds (select one)	
- Discharge – normal hip.	
- Planning surgery for closed/open reduction	
- Other	
[If follow-up ultrasound] When is the scan – X weeks	(range 1 - 8 weeks).
[If follow-up ultrasound] Have you started treatment today?	Y/N (select one).
[If Yes to started treatment] What is the treatment? (select one)	
• Observation	
• Abduction device (select one)	
■ Pavlik Harness	
■ Fixed Abduction Harness	
■ Other.	