Research Protocol
Version 1. – 5th August 2011

Full title
The development of an evidence based typology of Speech and Language Therapist led Interventions, incorporating the perspectives of families and children.

Short Title
Child Talk - What Works, Phase I

Proposed start date: 15th September 2011
Proposed end date: 14th September 2012

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1) Background and justification for the study

Children with speech and language impairments (SLI) are commonly classified into two broad groups, primary and secondary. Primary SLI exists in apparent isolation from any other identifiable condition. Secondary SLI is associated with other sensory, neurological and developmental conditions such as hearing loss, autism and learning difficulties. It is not always possible to distinguish clinically between primary and secondary SLI, particularly during the pre-school years, since a child's emerging language, cognition and other developmental processes closely interact, particularly where the developmental or neurological condition is not severe. This project relates to children with primary speech and language impairment (PSLI), with the acknowledgement that this is not always a distinct diagnostic group during the pre-school years.

Children with PSLI constitute a significant and important group. PSLI is one of the most prevalent of childhood developmental disorders, around 6% for children up to seven years old (1).   Research demonstrates that children with PSLI have an increased risk of difficulties in spelling and constructing written narratives, and reading disabilities and an association with behaviour difficulties is also a common finding (2,3).   Research further suggests that PSLI is a relatively stable long term condition that can persist into adulthood with an increased likelihood of cognitive and literacy difficulties, mental health issues, social isolation and poorer employment prospects (4,5,6).

There is increasing emphasis on the role of communication in securing a child's broader wellbeing. It is argued that poor communication is a risk factor in the maltreatment of children and for criminal offending (7,8). Government policy and initiatives stress the critical role that speech, language and communication play in a child's life, health and well-being (9,10,11). Furthermore, research has shown that different speech and language therapy (SLT) services have different impacts on patient outcomes and discharge patients at different points in their intervention pathway (12-15).

SLT-led interventions have been characterised in a number of ways, for example, as direct or indirect; as didactic, naturalistic or hybrid approaches; as therapist-centred, parent-as-therapist aide, family-centred and family-friendly (13,16,17). There are overlaps between these ways of conceptualising SLT-led interventions. None, however provide an overarching analysis of the principles, characteristics and components and associated outcomes that would allow systematic evaluation of the active ingredients. This lack of analysis means that it is difficult to stratify interventions according to their suitability for differing subgroups of children and families.

Systematic reviews of interventions for children with PSLI have concluded that there is evidence to suggest their effectiveness (12-18). However for some aspects of speech and language, the evidence is either mixed or unavailable, and strategies that are successful in the context of universal or targeted services are largely

unproven with children with identified PSLI. Interventions that have been included in reviews are heterogeneous and it is unclear from reviews which elements of any particular intervention constitute the active ingredients, which, if varied, might bring about differential results for subgroups of a population.

This exploratory project forms the first phase of a three year programme of work 'Evidence based interventions for Pre-school Children with Primary Speech and Language Impairments' (Child Talk - What Works) funded by an NIHR Programme Grant for Applied Research (PGAR), to build understanding and evidence regarding interventions that are ecologically valid and effective for pre-school children with PSLI. 'Pre-school children' covers children from birth - 5 years 11 months. The overall aim of the research programme is to improve the quality of SLT services for preschool children with PSLI, by producing evidence based intervention framework and associated toolkit which practitioners can use to stratify interventions to target the needs of child, taking into account the child's environment, family perspectives and resource limitations.

The data from this study on current beliefs and practices, will thus contribute to the development of the evidence based typology of SLT-led interventions for pre-school children with PSLI.

2) Study aims and objectives

The overall aim of the research programme is to improve speech & language therapy services for preschool children with primary speech & language impairments (PSLI). This will be achieved by developing an evidence based approach to intervention that integrates research evidence with SLT practitioner consensus and the perspectives of families, in a model that improves the targeting and stratification of interventions to meet the needs of the individual child and the characteristics of the family.

The aim for phase I of the programme of work is to develop an evidence-based typology of Speech and Language Therapist (SLT) - led interventions for preschool children with PSLI, which incorporates the experiences of families.

3) Research questions:

1. What do SLT practitioners perceive to be the critical components of intervention for preschool children with PSLI?
2. What child and family /contextual factors cause SLT practitioners to modify interventions provided and targets set?
3. In what ways do SLT practitioners modify interventions and targets in response to those factors?
4. How do SLT practitioners, non-SLT professionals and families understand interventions and their effectiveness?
5. How do families and children experience different approaches to interventions?
6. What factors influence whether or not families would access and actively engage with interventions?
7. What economic health resources are utilised by the various components of interventions by SLT's?

4) Research Summary

This research project is the exploratory phase of the research programme Child Talk – What Works and will use a mixed methods approach, incorporating interviews,

observations, focus groups and electronic surveys. This project will identify the types of interventions currently being used by SLTs throughout England, determine how and why SLTs adapt their use of interventions and targets according to child/family contexts, determine the perspectives of families about the interventions their children have received/been offered and why some families/communities are not engaging with these services. To do this the research team will identify case study sites within England that represent a range of SLT service types, locations and users. The first case study site will be Bristol, other sites will be identified using a matrix to guide the sampling. Appropriate approvals will be sought at that stage. It anticipated that we will require 6 case study sites.

Through these case study sites, and with support of the NHS service managers, we will invite SLTs, and parents to take part in focus groups. We will also identify families and /or communities that do not currently access SLT services within the local area and undertake participatory projects with these groups to gain their perspectives on the importance of communication and communication outcomes.

Since the target population for this research is preschool children with PSLI, there are limitations to the level of participation that is possible to achieve. However, it is important not to assume that we cannot access the perspectives of these children regarding interventions. With the support of case study sites, we will identify local children's groups (e.g. nurseries) where we will undertake pre-school focus groups with the children participating in activities such as storytelling.

In addition to the SLT focus groups we will explore the themes emerging from the focus groups through electronic surveys which will be distributed to SLTs in England. The focus groups and surveys will therefore be interacting, so that, as themes emerge from the focus groups, we will explore these themes more widely through the surveys and also explore in more depth the themes emerging from the surveys through the focus groups. The surveys will be iterative and distributed in a targeted manner through SLT service managers in England. Data collection and analysis will proceed iteratively until saturation is achieved (i.e. no further factor/topics are identified).

It is anticipated that we will need a minimum of six case study sites and 4-6 electronic surveys to achieve this. This research project will be led by North Bristol NHS Trust in collaboration with Manchester Metropolitan University with the research team being split across the two sites.

5) Research Design and Methodology

i. Focus groups for SLTs who work preschool children with PSLI
ii. Focus groups for non-SLT professionals who work with preschool children with PSLI
iii. Focus groups of parents of children with PSLI
iv. Pre-school children group sessions
v. Participatory projects with families who do not typically access SLT services in that location.
vi. Electronic surveys

Selection of Participant Identification Centres (PICs)

In order to assess the range and types of interventions currently being delivered

through SLT services, and the family perspectives on the interventions they have received we will identify NHS SLT services to be used as case study sites. NHS SLT services which offer interventions for preschool children with PSLI in England will be approached via email in the first instance. Service manager email lists are available through the professional leads and managers' network of the Royal College of Speech & Language Therapists (RCSLT). Access to this will be facilitated by the research programme Advisory Group member Hazel Roddam, Chair of RCSLT. Services will be targeted using purposive sampling to ensure a range of interventions, service sizes and structures, and in order to investigate a full range of population demographics (e.g. urban/rural, socio-economic status, educational background, proportion of bilingual families, refugees, first and second generation immigrant populations etc.). On receipt of an expression of interest from a service manager a phone call will be made by a member of the research team to determine the eligibility of their service, the general demographics of their population, the range of interventions offered to preschool children with PSLI, staffing levels and expertise. The research team will then select case study sites and through which the service manager will distribute information regarding the study to SLTs and parents within the service. The service will be added as a Participant Identification Centre (PIC) and R&D approval sought. The research team will undertake all recruitment and consenting of SLTs and parents for the focus groups, and pre-school children group sessions identified through those sites. The first case study site will be Bristol, service manager Jenny Moultrie (research programme co-applicant).

5.1 Focus groups with non-SLT professionals who work with preschool children with PSLI

5.1.1 Participants
Currently practising NHS Speech and Language Therapists, with at least two years' experience of working with children with PSLI.

In order to sample a range of experience within this specialist field of practice, it might be necessary to recruit SLTs from a wider range of services than the prime case study sites. In this case we will also recruit SLTs via Special Interest Groups (SIGs) (groups of SLTs who have a common focus and who meet at regional or national level) and from services adjoining the PICs, but not NHS).

5.1.2 Methodology
Within the PICs, service leads will be asked to distribute an invitation to participate, via email, to staff who meet the inclusion criteria. Staff will be asked to reply to the research team at North Bristol Trust (NBT) via email, indicating their interest in participating in the study. Following the expressions of interest, a member of the research team will contact each individual and ask for brief details about their work and experience, in order to ensure a range of participants are present in each focus group. A purposive selection of a maximum of 42 participants will then be made. A focus group will typically be made up of 4-8 participants and each participant will be asked to participate in 1 group only. Participants will be purposively selected to obtain a range of experience (e.g. length of time working with this group of children; range of interventions being delivered). Those respondents who are not selected to be interviewed will be informed and thanked for their interest. A member of the research team will phone selected participants to give them an opportunity to discuss the research further and answer any questions they might have. If they are still willing to participate, the selected participants will be sent a participant information sheet, a topic guide, a copy of the consent form and proposed date of focus group. Two copies of the consent forms will be signed at the focus group by the participant and a

member of the research team, one copy will be retained by the participant and one stored in the study file. It is anticipated that the focus groups will not be held on NHS sites, but if this is not the case appropriate permissions will be obtained including R&D approval. Focus groups are expected to last up to 1.5 hours.

Focus groups will be face-to-face facilitated by a moderator and a note taker (both members of the research team) and will be recorded using a digital audio and video recorder, and supplemented by the research team's field notes. The video recording will be used to disaggregate speakers if difficult from the audio recordings. The focus groups will have a semi-structured format, using a combination of:

     i.   Ground rules for discussion, including confidentiality
    ii.   Discussion of data presented by the researchers, on intervention activities and strategies
   iii.   Open discussion of critical components of intervention
   iv.   Open discussion about modification of intervention – causes and practice
    v.   Discussion of fictional vignettes to allow further discussion of i-iii above

5.1.3 Data Analysis

SLT focus group data will be transcribed orthographically. As the data are being transcribed, the data will be made anonymous by removing names of people, school, locations and any other identifying information. Transcription will be carried out by project research assistants, supervised by senior researchers. Two methods of analysis will be used for the SLT focus group data. Firstly, content analysis will be used in order to extract terms used by the participants to describe their work in relation to intervention, targets and modifications. These data will help to populate the electronic surveys. Secondly in order to analyse the range of practice, analysis will be carried out by more than one research assistant using the structured approach provided by the 'Thematic Network Analysis' (Attride-Stirling 2001). Qualitative data analysis will be supported by the use of NVIVO software.

5.2 Focus groups with non-SLT professionals who work with preschool children with PSLI

5.2.1 Participants

Non-SLT professionals such as Early Years Practitioners (EYP) or Children's Centre staff, with at least two years' experience of working with children with PSLI and who are currently working with preschool children with PSLI.

5.2.2 Methodology

Within the PICs, service managers will be asked to nominate Early Years/Children's Centre sites in their area. The research team will make direct contact with the site managers and arrange to meet and discuss the study and obtain appropriate approval. The site manager will be asked to distribute invitations to participate, via email, to staff within their service who meet the inclusion criteria. Staff will be asked to reply to the research team at NBT via email, indicating their interest in participating in the study. Following this expression of interest, the non-SLT professionals will be telephoned and asked for brief details about their work and experience (e.g. length of time working with this group; experience of children with PSLI). This information will be used to ensure a range of participants are present in each focus group. From the expressions of interest and subsequent telephone screening, a purposive selection of a maximum of 42 participants will then be made. Focus groups will typically be made up of 4-8 participants. Those people expressing an interest but who are not selected to be interviewed will be informed and thanked for their interest.

A member of the research team will phone selected participants to give them an opportunity to discuss the research and answer any questions they might have. The selected participants will be sent a participant information sheet, a topic guide, a copy of the consent form and proposed date of focus group. Two copies of the consent forms will be signed at the focus group by the participant and a member of the research team, one copy will be retained by the participant and one stored in the study file.

It is anticipated that the focus groups will not be held on NHS sites, but if this is not the case appropriate permissions will be obtained, including R&D approval. Focus groups are expected to last up to 1.5 hours. Topics will focus on non-SLT professionals' views of the key components of interventions and how these are varied for the individual child. A range of open discussion, vignettes and guided discussions will take place, similar to the SLTs but adjusted for the different knowledge bases of these professional groups.

Focus groups will be face-to-face and will be recorded using a digital audio and video recorder, and supplemented by the research team's field notes. The video recording will be used to disaggregate speakers if difficult from the audio recordings. The focus groups will have a semi-structured format, using a combination of:

i. Ground rules for discussion, including confidentiality
ii. Discussion of data presented by the researchers, on intervention activities and strategies
iii. Open discussion of critical components of intervention
iv. Open discussion about modification of intervention – causes and practice
v. Discussion of fictional vignettes to allow further discussion of i-iii above

5.2.3 Data Analysis
Non-SLT professional focus group data will be transcribed orthographically. As the data are being transcribed, the data will be made anonymous, by removing names of people, school, locations and any other identifying information. Transcription will be carried out by project research assistants, supervised by senior researchers. Two methods of analysis will be used for the practitioner focus group data. Firstly, content analysis will be used in order to extract terms used by the participants to describe their work in relation to intervention, targets, modifications etc. Secondly in order to describe the *range* of practice, analysis will be carried out by more than one research assistant, using the structured approach provided by the 'Thematic Network Analysis' (Attride-Stirling 2001). Qualitative data analysis will be supported by the use of NVIVO software.

5.3 Focus groups with parents accessing SLT services

5.3.1 Participants
Parents of pre-school children (up to 5yr 11months) with PSLI (or with suspected PSLI) who currently access, or who have recently accessed, SLT services.

5.3.2 Methodology
Within the PICs, the service manager will be asked to identify parents/guardians of children with (or suspected to have) PSLI currently on the SLT service caseload. In order to minimise the burden placed on the service manager, a member of the research team will attend the PIC and prepare postal invitations to send to parents/guardians. The invitations will include an invitation letter sent from the

service manager, reply slip and a prepaid envelope for returning reply slips. Letters and envelopes will be written (mail merged) at each PIC and posted from those sites, thus ensuring that identifiable data is not removed from the site by the research team.

Parents will be sent this accessible information about the research programme and the focus groups and invited to return expressions of interest to the research team. All documentation sent to parents will be reviewed by our parent research partners (section 11). Once an expression of interest has been received a member of the research team will contact the parents/guardians and ask for information such as postcode, job, years of education, family circumstances, and SLT services received. From this information parents/guardians will be purposively selected based on socio-economic background, linguistic background, SLT service experience, age of preschool child, and severity of the child's difficulties. Those respondents who are not selected to be interviewed will be informed and thanked for their interest. The selected parents/guardians will be sent a participant information sheet, a topic guide, a copy of the consent form and proposed date of focus group. A member of the research team will phone selected parents to give them an opportunity to discuss the research and answer any questions they might have. Two copies of the consent forms will be signed at the focus group by the parents and a member of the research team, one copy will be retained by the parent and one will be stored in the study file. It is anticipated that the focus groups will not be held on NHS sites, but if this is not the case appropriate permissions will be obtained including R&D approval. Focus groups are expected to last up to 1.5 hours.

Focus groups will be face-to-face and will be recorded using a digital audio and video recorder, and supplemented by the research teams field notes. The video recording will be used to disaggregate speakers if difficult from the audio recordings. The focus groups will have a semi-structured format, using a combination of:

i. Ground rules for discussion, including confidentiality
ii. Discussion of parents understanding of their child's difficulties
iii. Discussion of parents views/experiences of SLT-led interventions offered to their children
iv. Discussion of parents views about active components of interventions
v. Discussion of parents views of relevant outcomes for their children
vi. Parental Contribution and participation in selection of intervention, intervention delivery and setting of attainment targets

If there is insufficient interest from parents in participating in the structured focus groups, the research team will work with our parent research partners to determine the most appropriate method for engaging with these parents, e.g. mums and toddler groups, and, if required, appropriate approvals will be sought for this from those sites.

5.3.3 Data Analysis
Parent focus group and interview data will be transcribed orthographically. As the data are being transcribed the data will be anonymised, by removing names of people, school, locations and any other identifying information. Transcription will be carried out by project research assistants, supervised by senior researchers. Two methods of analysis will be used for the practitioner focus group data. Firstly, content analysis will be used in order to extract terms used by the participants to describe their work in relation to intervention, targets, modifications etc. Secondly in order to describe the range of practice, analysis will be carried out by more than one research assistant, using the structured approach provided by the 'Thematic Network Analysis'

(Attride-Stirling 2001). Qualitative data analysis will be supported by the use of NVIVO software. For this set of data, an additional level of analysis will be used (compared to the SLT and practitioner focus group data), as the purpose is to explore parents' views and experiences of services for their children with PSLI.

5.4 Participatory groups with families who do not currently access SLT services

5.4.1 Participants
Families/communities who do not currently access services. This could be through direct identification of parents through service managers (section 5.3) of children with (or suspected to have) PSLI who have been referred but have not attended SLT sessions. Secondly, participants will be identified within local communities from which SLT referrals are infrequently made / or taken up. This could involve vulnerable and socially excluded families, such as traveller communities and some ethnic/linguistic minority groups.

5.4.2 Methodology
Within the PICs the research team will consult with the service managers to determine types of families/communities within that local area who do not engage with their service.

Families/communities local to the case study area who do not engage with services will be contacted with the support of community organisations such as Barnardo's. One-off group sessions may not be successful in engaging with these families. With the assistance of the community organisations and participation workers, we intend to work with the families themselves to tailor the techniques of data elicitation to their context and culture. This will be a participatory process to facilitate engagement and to identify a context within which they will be able to explore and communicate their views about the nature of communication, communication impairment and its remediation. In order to form relationships with these families, an extended period of contact may be required, using a combination of group based activities and individual interviews. We anticipate there will be a maximum of three interviews per family, and two group based sessions per identified community (such as travellers, single parents, ethnic minority). These will take place in non-NHS settings in which the participants are comfortable (but not in their homes), such as local village halls. Parents/families will be recruited from the community rather than through the NHS. In collaboration with parent research partners, community organisations, local participation workers and NHS translators, we will ensure all communication with these families is appropriate and that informed consent is obtained.

5.4.3 Data Analysis
The data analysis used will depend on the data collected and the researchers will in part be guided by the participatory workers' views. Data is likely to be in several formats. Audio and video data will be transcribed orthographically as described above. Photographs and field notes will be used together with the transcripts and analysed thematically, drawing on ethnographic approaches, in order to describe families' ideas about communication disability, services to support their children and engagement in intervention for children with PSLI.

5.5 Preschool children with PSLI group sessions

5.5.1 Participants

Preschool children (up to 5yrs 11months) with PSLI who currently receive SLT-led interventions and preschool children from families who do not currently access SLT services.

5.5.2 Methodology
Participants will be based in existing children's settings (such as a playgroup or nursery). These settings will be identified with the support of the SLT managers in each case study site. The research team will make direct contact with the children's setting manager and arrange to meet and discuss the study and obtain appropriate permissions. The recruitment of children within each of the children's settings will be through the informed consent of the parents.

The site manager will be asked to distribute invitations to participate, to parents and a member of the research team will prepare envelopes for sending to parents with an invitation letter, reply slip and a prepaid envelope for returning reply slips. Parents will be sent this accessible information about the research programme and the focus groups and invited to return expressions of interest to the research team. All documentation sent to parents will be reviewed by our parent research partners (section 11). A member of the research team will discuss the research with parents prior to the observational study and obtain consent.

Due to the age of the participating children it is not possible to obtain 'consent' however we will seek 'assent' from children. The task will be explained in suitable language to the children by experienced members of the research team. Their participation will be taken as 'assent'. If at any point during the session the child withdraws from the activity they will be encouraged to reengage in a similar fashion as they would be used to within a nursery setting. If they continue to display a desire to stop it will be taken as a removal of assent and the child will be safe guarded until the end of the session when they will be collected by their parents/guardians.

These sessions with children will explore their experiences, needs and perceptions of interventions identified through the SLT focus groups. These will include play-based and creative arts based methods such as music or painting or arts based such as story telling techniques. These techniques will be chosen following consideration of the cultural context, familiarity and likely responsiveness of the participants to particular activities. For example, storytelling is a known context for children; stories can be created in which children participate and thereby show their perspectives on a certain question; stories can be created about SLT interventions that allow children to indicate how they might feel about such intervention. These interventions will be audio and video recorded, and supplemented with researcher field notes and photographs of any output created by the children during the session. There will be four children's groups per case study site.

5.5.3 Data Analysis
Data from the observations of children (both those accessing and those not accessing services) will be in several formats:

    i.   Drawings and paintings
    ii.   Narratives
    iii. Researcher field notes
    iv. Photographs
    v.   Video and audio recordings

Audio and video data will be transcribed orthographically as described above. Photographs and field notes will be used together with the transcripts and analysed

thematically, drawing on ethnographic approaches, in order to describe children's ideas about intervention for PSLI.

5.6 Electronic surveys

5.6.1 Participants
Currently practising Speech and Language Therapists with at least two years' experience working with children with PSLI and currently working with preschool children with PSLI. Participants may be based at the NHS, children's' services, the voluntary sector (Non-governmental Organisations, NGOs) or the private sector,

5.6.2 Methodology
NHS services within England will be selected to represent a range of demographics and service types. A member of the research team will email service managers inviting them to distribute, via email, the electronic survey to staff within their service who meet the inclusion criteria. The distribution of the survey will include but not be limited to case study sites. Services through which the survey will be distributed will be added as a PIC and appropriate approvals will be sought from NHS Trusts prior to distribution. The service mangers email addresses are available through the managers' network of the Royal College of Speech & Language Therapists (RCSLT). Access to this will be facilitated by the research programme Advisory Group member Hazel Roddam, Chair of the RCSLT. If recruitment via service managers is insufficient, then a number of other methods will be used to maximise response rates, including advertising in national SLT professional magazines, advertising on the RCSLT website and via SLT research email network. These methods of recruitment will capture SLTs working both within and outside of the NHS. If national advertising is to be undertaken, appropriate approvals will be sought.

The survey will be distributed iteratively and a process of rolling recruitment will be used for successive surveys so that the same participants are not overused, for example by sampling different managers for each survey. The first survey will be based on aspects of the data collected through the SLT focus groups in Bristol. Subsequent surveys will investigate further aspects themes emerging from the SLT focus group data and the first survey. We anticipate 4-6 iterations of the survey, but distribution will continue until saturation of themes is achieved. The design of the survey is dependent on the outcomes of the focus groups but is likely to include:

    i.   Participant information (non-identifiable) and consent tick box
    ii. Basic biographic data (non-identifiable)
    iii. Broad caseload data (numbers of groups of patient types, but no details about individual patients)
    iv. Work location
    v. Intervention strategies and activities used
    vi. Influences on decisions about intervention activities and strategies
    vii. Target setting
    viii. Influences on decisions about target setting

Items will include closed questions, multiple choices, open questions; items based on *'True to Life'* vignettes with discrete choice questions. The first distribution of the survey will be within the first case study site in Bristol, following the first SLT focus groups. The surveys will be made anonymous, with no personal identifiable information being requested.

5.6.3 Data Analysis

The purpose of the surveys is to gather data about the range of practice and not quantitative inferential data (such as the proportion of different types of practice and contextual factors and the relationships between them and other variables). Therefore data analysis will primarily be quantitative, using descriptive statistics to summarise the themes that emerge (SPSS, v 17). Content analysis will also be utilised in order to extract terms used by the respondents to describe their work in relation to intervention, targets and modifications. If sufficient free-text data is supplied to open questions then it may be possible to undertake Thematic Network Analysis (Attride-Stirling, 2001).

6. Service Evaluation

In addition to and supporting this research project will be an ongoing service provision review to determine the care pathways in place for children with PSLI within NHS SLT services in England. This is a separate service evaluation which will be undertaken by the research team.

7. Evaluation of Economic Resource use

Part of the research programme (Child Talk – What Works) will be to determine the health economic resource use associated with different types of services and intervention. The information collected as part of the focus groups alongside the service evaluation, will be analysed by Health Economists, Dr Jane Powell, University of the West of England and Dr Will Hollingworth, University of Bristol (programme grant co-applicants) to determine the resource use associated with different types of interventions in different contexts. This resource evaluation will support the development of the intervention toolkit in phase 2 of the research programme.

8. Data Management

All research data will be managed in accordance with the Data Protection Act (1998). Manchester Metropolitan University will lead data collection/analysis of SLT focus groups and electronic survey. NBT will lead the data collection and analysis of non-SLT professional focus groups, parent/guardians focus groups and the studies of children. All original electronic data containing personal identifiable information will be stored in an encrypted folder at NBT following transcription and anonymising by a member of the research team. This encrypted folder will require a password for access. Personal identifiable information will be kept for 10 years in line with NIHR requirements and the files will be tagged with a destruction date. At times data may need to be transferred between sites and files will be password protected and emailed. The transfer of password protected files containing identifiable information between NBT and Manchester Metropolitan University (MMU) will be kept to a minimum. All paper based study related documentation including consent forms will be stored in a locked filing cabinet in the Speech and Language Therapy Research Unit at NBT. Access to the unit is via a key pad.

9. Ethical Considerations

The research programme focuses on interventions for a vulnerable group, that is, young children. All members of the team who will have contact with the children will have Criminal Records Bureau Enhanced Clearance and receive appropriate training

in procedures for safeguarding children. In addition we will be working with families for whom communication may be difficult, for whom English is not their first language or is not spoken. Local participation workers and NHS translators will be employed to support effective engagement with these groups. The research programme has collaborators and advisors who are experienced in working with children and adults with communication disability and any new team members will receive appropriate training and support from experienced members. Ethics approvals to undertake this study will also be sought from MMU and University of the West of England (UWE).

10. Expertise on Programme Grant team

The research team, led by Prof. Sue Roulstone and Dr Julie Marshall, will undertake the data collection and analysis. In addition the research programme has co-applicants who will bring their expertise to support the delivery of this research and to advise on methodology, data collection and analysis.

- Dr Will Hollingworth (UoB) - Health Economics
- Dr Jane Powell (UWE) – Health Economics
- Prof. Tim Peters (UoB) – Statistics/research design
- Mrs Jenny Moultrie (NBT) - Professional lead in Speech and Language Therapy
- Prof. Jane Coad (Coventry University) - Engagement of children using art-based methods
- Prof. Norma Daykin (UWE) - Innovative arts methods of data collection
- Prof. Juliet Goldbart (MMU) - Working with parents in diverse settings
- Prof Alan Emond (UoB)- Child health services delivery and evaluations
- Prof Jon Pollock (UWE)- Research design, evaluation and implementation processes
- Dr Yvonne Wren (NBT) - Development of measurement tools
- Mr Cres Fernandes (AR Assessment Ltd)- Specialist adviser in psychometrics
- Mrs Linda Lascelles (Afasic) - Support for engaging parents of children

11. Public Patient Involvement (PPI)

Afasic, Supportive Parents and Barnardo's have consulted and collaborated with the PI in developing the grant application, and will continue to collaborate throughout the research programme. In addition the research team are setting up a three tiered approach to public patient involvement to identify the most appropriate method for engaging parents as research subjects and to review all consent forms and participation sheets:

- 2-3 parent research partners will collaborate with the research team and attend advisory group meetings (local)
- A panel of parents who represent families who do and do not currently access services will review any documentation that will be sent to research participants (national)
- Parents/families/peers from vulnerable/socially excluded communities to be accessed, with support from community organisations, will collaborate in developing strategies and documentation to engage with these communities (to be identified during the case studies).

Through the expertise of the PI, research team, programme collaborators and PPI we will ensure that we engage with children, parents and vulnerable groups in an appropriate manner and that all communication (oral, written) is prepared in language that is relevant to, and appropriate for, the target audiences.

12. Dissemination

The findings from this research project will be disseminated through Conference presentations, (for example RCSLT biennial conference, national Special Interest Groups) and papers in peer reviewed journals (for example the International Journal of Language and Communication Disorders). Results will also be disseminated through our PPI network. The findings from this study will feed into phase 2 of the research programme.

Outputs from the research programme as a whole will include measurement tools, guidelines, the evidence based typology and a national outcomes framework. The research team will target policy, practice, education for practitioners and public and family awareness when disseminating the findings. As well practitioner journals, peer reviewed articles, the programme will deliver a seminar series that will disseminate the key findings and discuss implementation issues with key stakeholders. At the end of the programme, we will organise a joint stakeholder conference with RCSLT and AFASIC, (including SLT managers and commissioners) to consider the implications of the programme for possible restructuring of SLT service commissioning and the delivery of SLT services for pre-school children with PSLI.

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14. Appendices

14.1 Case studies
    14.1.1 Invitation to Speech and Language Therapy Services Managers
    14.1.2 Flow Chart

14.2 SLT focus Groups
        14.2.1 Invitation to SLTs (via service manager)
    14.2.2 Flow Chart
    14.2.3 Participatory Information Sheets
    14.2.4 Consent form for SLTs – Focus Group
    14.2.5 Topic guide

14.3 Practitioner Focus Group
    14.3.1 Invitation to Practitioners (via site manager)
    14.3.2 Flow Chart
    14.3.3 Participatory Information Sheets
    14.3.4 Consent form for Practitioners – Focus Group
    14.3.5 Topic guide

14.4 Parent Focus group
    14.4.1 Invitation to SLTs (via service manager)
    14.4.2 Flow Chart
    14.4.3 Participant Information Sheet
    14.4.4 Consent form for Parents – Focus Group
    14.4.5 Topic guide

14.5 Participatory groups (Not accessing SLT services)
    14.5.1 Flow Chart
    14.5.2 Participant Information Sheet
    14.5.3 Consent form for Participatory groups

14.6 Preschool Children Groups
    14.6.1 Flow Chart
    14.6.2 Participant Information Sheet
    14.6.3 Consent form for Parents – Childrens Group

14.7 Electronic Survey
    14.7.1 Invitation to NHS SLT service managers to distribute electronic survey (from   research team)
    14.7.2 Invitation to Speech and Language Therapists to complete an electronic   survey (via service manager)

Phase two protocol

Research Protocol
Version 1.

Full title
The Development of a National Outcomes Framework through Consensus

Short Title
Child Talk - What Works, Phase II

Proposed start date: 1st February 2013
Proposed end date: 31st December 2013

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1. Background and justification for the study

Children with speech and language impairments (SLI) are commonly classified into two broad groups, primary and secondary. Primary SLI exists in apparent isolation from any other identifiable condition. Secondary SLI is associated with other sensory, neurological and developmental conditions such as hearing loss, autism and learning difficulties. It is not always possible to distinguish clinically between primary and secondary SLI, particularly during the pre-school years, since a child's emerging language, cognition and other developmental processes closely interact, particularly where the developmental or neurological condition is not severe. This project relates to children with primary speech and language impairment (PSLI), with the acknowledgement that this is not always an easily identifiable and distinct diagnostic group during the pre-school years.

Children with PSLI constitute a significant and important group. PSLI is one of the most prevalent of childhood developmental disorders, around 6% for children up to seven years old (1). Research demonstrates that children with PSLI have an increased risk of difficulties in spelling and constructing written narratives, and reading disabilities and an association with behaviour difficulties is also a common finding (2,3). Research further suggests that PSLI is a relatively stable long term condition that can persist into adulthood with an increased likelihood of cognitive and literacy difficulties, mental health issues, social isolation and poorer employment prospects (4,5,6).

There is increasing emphasis on the role of communication in securing a child's broader wellbeing. It is argued that poor communication is a risk factor in the maltreatment of children and for criminal offending (7,8). Government policy and initiatives stress the critical role that speech, language and communication play in a child's life, health and well-being (9,10,11). Furthermore, research has shown that different speech and language therapy (SLT) services have different impacts on patient outcomes and discharge patients at different points in their intervention pathway (12-16).

SLT-led interventions have been characterised in a number of ways, for example, as direct or indirect; as didactic, naturalistic or hybrid approaches; as therapist-centred, parent-as-therapist aide, family-centred and family-friendly (13,14,18). There are overlaps between these ways of conceptualising SLT-led interventions. None, however, provide an overarching analysis of the principles, characteristics and components and associated outcomes that would allow systematic evaluation of the active ingredients. This lack of analysis means that it is difficult to stratify interventions according to their suitability for differing subgroups of children and families.

Systematic reviews of interventions for children with PSLI have concluded that there is evidence to suggest their effectiveness (13-19). However, for some aspects of speech and language, the evidence is either mixed or unavailable, and strategies that are successful in the context of universal or targeted services are largely unproven with children with identified PSLI. Interventions that have been included in

reviews are complex and it is unclear from reviews which elements of any particular intervention constitute the active ingredients, which, if varied, might bring about differential results for subgroups of a population.

This project forms the second phase of a three year programme of work 'Evidence based interventions for Pre-school Children with Primary Speech and Language Impairments' (Child Talk - What Works) funded by an NIHR Programme Grant for Applied Research (PGAR), to build understanding and evidence regarding interventions that are ecologically valid and effective for pre-school children with PSLI. 'Pre-school children' covers children from birth - 5 years 11 months. The overall aim of the research programme is to improve the quality of SLT services for preschool children with PSLI, by producing an evidence-based intervention framework and associated toolkit which practitioners can use to stratify interventions to target the needs of child, taking into account the child's environment, family perspectives and resource limitations.

Phase I
The aim of Child Talk – What Works phase I was to develop an evidence-based typology of Speech and Language Therapist (SLT) - led interventions for preschool children with PSLI, which incorporates the experiences of families. This used a mixed methods approach, incorporating interviews, observations, focus groups, electronic surveys and systematic reviews. This identified the types of interventions currently being used by SLTs throughout England, determined how and why SLTs adapt their use of interventions and targets according to child/family contexts, explored the perspectives of families about the interventions their children have received/been offered and why some families/communities are not engaging with these services.

Phase II
The data from phase I of this research programme has been used to develop an evidence based typology of SLT-led interventions for pre-school children with PSLI. Phase II will further develop this typology, though exploring stakeholder perspectives and consensus, into an intervention framework with an assessment toolkit.

2. Study aims and objectives

The overall aim of the research programme is to improve speech & language therapy services for preschool children with primary speech & language impairments (PSLI). This will be achieved by developing an evidence based approach to intervention that integrates research evidence with SLT practitioner consensus and the perspectives of families, in a model that improves the targeting and stratification of interventions to meet the needs of the individual child and the characteristics of the family.

The aim of phase II of the programme of work is to develop an intervention framework and toolkit that can form the basis of follow on research, to establish effectiveness and cost-effectiveness and that can be used by commissioners and services nationally to plan services and future evaluations.

The research team will achieve the aim by:
- Investigating and establishing consensus amongst stakeholders regarding the generalisability, applicability and acceptability of the typology developed from Child Talk – What Works phase I.

- identifying key measures that can be used to determine the most appropriate child and family-specific interventions

- identifying measures that can be used to assess the outcomes and cost-effectiveness of those interventions

3. Research Design and Methodology

vii. Consensus building exercises with a range of participants to develop an intervention framework.

viii. Development of an assessment toolkit to support the intervention framework.

3.1 Consensus Building

The consensus building exercise will involve exploring the views of a wide range of participants and stakeholders on the typology of practice that has emerged from phase I and identifying areas of consensus. This will be achieved using an iterative, staged, approach to explore consensus within stakeholder groups and drawing together all of the perspectives. A variety of methodologies will be used including, Nominal Group, World Café and Delphi exercises to explore consensus as well as surveys and more innovative methods such as use of the web to engage with a wide audience. Recruitment will take place through one NHS site, Bristol, as well as through community settings, the media and professional bodies.

3.1.1 Stage 1 - Speech & Language Therapists

The first stage of the consensus building aims to explore the view of Speech and Language Therapists on the typology that has emerged from Phase I of Child Talk – What Works. A set of statements will be generated that reflects current evidence and opinion about particular components of interventions. Participants will be asked to identify gaps, rank statements in order of priority and expand on statements using nominal group, world café and Delphi consensus groups.

a. Participant recruitment

The inclusion criteria is, currently practising NHS Speech and Language Therapists and assistants with experience of working with children with primary speech and language impairments.

In order to sample a range of experience within this specialist field of practice, it will be necessary to recruit Speech & Language Therapists from a wide range of services. Recruitment will take place at one NHS Speech and Language Therapy services, Bristol. In addition, SLTs and service managers will be invited through professional body networks, with the support of the Royal College of Speech & Language Therapists (RCSLT) and the Association of Speech and Language Therapists in Independent Practice (ASLTIP).

The SLT service manager at the study site in Bristol will be asked to distribute an invitation to participate, via email, to staff who meet the inclusion criteria. Staff will be asked to reply to the research team at NBT via email, indicating their interest in participating in the study.

In addition to recruiting through the NHS, we will also recruit participants more widely through professional bodies. We will work with the Royal College of Speech & Language Therapists (RCSLT) and the Association of Speech and Language Therapists in Independent Practice (ASLTIP) to distribute emails inviting participants to express an interest to take part.

A member of the research team will phone participants who have expressed an interest in taking part to give them an opportunity to discuss the research further and answer any questions they might have. If they are still willing to participate, the selected participants will be sent a participant information sheet, a topic guide, a copy of the consent form and proposed date of a consensus group.

In addition to the above we would also seek RCSLT support in identifying existing groups, who meet regularly, that we could undertake a consensus group with, such as Early Years Special Interest Groups (SIGs) and regional hubs. In the case that the research team are invited to undertake a consensus exercise at an existing group meeting, such as a SIG, attendees will be sent the participant information sheet and consent form at least one week prior to the meeting and will be informed that if they do not wish to take part they do not need to attend that part of the SIG meeting (the consensus group would be held at the end of the SIG meeting).

b. Methodology
Two copies of the consent forms will be signed at the consensus group by the participant and a member of the research team, one copy will be retained by the participant and one stored in the study file. Appropriate R&D permissions will be obtained to allow consensus groups to take place on NHS premises to minimise disruption to SLTs workload, groups are expected to last up to 1.5 hours with at least 12 participants at each group. Consensus groups will be face-to-face lead by a moderator and supported by facilitators working with the individual groups (all members of the research team). The group activities will be recorded using a digital audio and video recorder, and supplemented by the research team's field notes. The video recording will be used to disaggregate speakers if difficult from the audio recordings. Outputs will also include notes written on flip charts, post-it and paper written by the participants during the groups. Following each consensus group, the list of typology statements will be further developed and this will be circulated to participants by email to ask them to rank, expand and identify gaps. It is anticipated that up to three iterations of the typology statements will be sent to participants via email following the group discussions. The level at which we would classify general agreement is 80%.

There is no formal sample size required for this type of methodology, except, the groups must be of manageable size. We will be undertaking groups until we have identified the level of agreement amongst SLTs on the ranking of statements and no gaps are being identified.

3.1.2 Stage 2 – Expert Reference Groups

The next stage will involve a series of validation exercises that will be carried out to identify any major theoretical or applied theoretical gaps in the typology. First, an expert reference group consisting of academic researchers and senior clinicians working in the field of preschool PSLI will be invited to comment on the typology followed by an RCSLT management board/leaders group. Finally the views of participants who took part in phase I of Child Talk – What Works will be invited to provide their views on the typology.

a. Participant Recruitment
Participants to this stage of the consensus building exercise will be selected and contacted directly be email or letter to invite them to take part. We will invite known preschool PSLI experts from academia, clinical practice and participants from phase I of the research programme to take part in the expert reference groups. The invited

participants will be asked to contact to the research team if they would like to take part at which point they will be sent a participant information sheet and consent form and details of the date, time and location of the group.

b. Methodology
Two copies of the consent forms will be signed at the expert reference group by the participant and a member of the research team, one copy will be retained by the participant and one stored in the study file. Groups will be held in non-NHS settings and will last for up to 1.5 hours. It is expected that we will hold eight reference groups (one academic, one RCSLT management and six with phase I participants). At each group the research team will present the typology to the participants and ask for their commentary/views. The group discussions will be recorded using a digital audio and video recorder, and supplemented by the research team's field notes. The video recording will be used to disaggregate speakers if difficult from the audio recordings. Outputs will also include notes written on flip charts, post it and paper written by the participants during the groups. Following each consensus group, the list of typology statements will be further developed and this will be circulated to participants by email to ask them to rank, expand and identify gaps. There is no formal sample size required for this type of methodology; however, we would aim for at least six participants at each reference group and a maximum of 20.

Following all of the expert reference groups, the list of typology statements will be further developed and this will be circulated to participants by email to assess the level of consensus. It is anticipated that up to three iterations of the typology statements will be sent to participants via email following the group discussions. The level at which we would classify general agreement is 80%.

3.1.3 Stage 3 – Parent Perspectives

The third stage of the consensus building will explore more widely the views of parents on the developing typology. This will be the most challenging group to recruit and so we will use a variety of methods to engage with parents and we will need to be innovative and flexible in our recruitment strategies. Consensus groups will be held where sufficient numbers of participants are recruited; in addition we will use the web to distribute surveys with videos introducing the typology to parents, written and delivered by our parent research partners as part of our PPI.

a. Participant Recruitment
The inclusion criteria is parents of children aged 7 or under who have been (or are) worried about their child's talking/learning to talk during their preschool years.

Recruitment will take place at the NHS Speech and language Therapy service in Bristol. SLT service managers at the study site will be asked to send letter in the post or to hand out letters during clinics inviting parent who fit the inclusion criteria to participate. Parents will be asked to reply to the research team at North Bristol Trust (NBT), via a reply slip enclosed with the letter of invitation, indicating their interest in participating in the study.

Parents will also be invited to take part through Children's centres. Nurseries, schools, advertising in the local community, health centres and GP surgeries, TV and radio advertising and websites such as Afasic and Netmums.

b. Methodology
A member of the research team will phone participants who have contacted us to

express an interest in taking part to give them an opportunity to discuss the research further and answer any questions they might have. We will obtain some basic information from the parents to ensure they fit the inclusion criteria. At this point we would obtain verbal consent to ask up to 5 questions, these will be an opinion/rating with regards to a statement describing a therapeutic approach/intervention/typology. The reasoning behind wanting to ask research questions at this point over the phone is based on the difficulties we have faced in recruiting parents to Phase 1 of Child Talk. It is desirable to capture information at the first point of contact in case they do not then turn up to focus groups or interviews. After the questions, the parents will be asked if they would consider participating in an event such as a coffee morning (focus group), individual interviews or online survey. If they are willing to participate, the participants will be sent a participant information sheet, a copy of the consent form and proposed date of the activity.

At the activity, two copies of the consent forms will be signed by the participant and a member of the research team, one copy will be retained by the participant and one stored in the study file. Appropriate R&D permissions will be obtained to allow activities to take place on NHS premises if necessary. We would ensure that the activities would not be expected to last more than 1.5 hours. Outputs will also include audio and video recording, notes written on flip charts, post it and paper written by the participants.

If preferred to the group work and individual interview, parents will be offered the option of taking part in an online survey. With the support of our parent panel, we will prepare a video that describes the typology in a way that is accessible and engaging to parents. This would be written and delivered by our parent panel (PPI). Following the video, parents would be asked to complete a short survey asking for their views on the typology. We would host the video and electronic survey on our research unit website and widely distribute the link on internet sites such as Afasic and Netmums. The survey would be anonymised. Consent for taking part in the survey would be through completion and submission of the electronic survey.

We will consult with the NIHR (funder) to develop any material that will be placed on the internet, any press releases for radio and TV and any information disseminated within the local community to ensure it complies with their communication policy.

There is no formal sample size required for this type methodology, rather, we will be undertaking groups and the survey until we have identified the level of agreement amongst parents on the ranking of statements and no gaps are being identified. The level at which we would classify agreement is 80%.

3.1.4 Stage 4 - National Perspective
The final stage of the consensus building will be a world café event to assess national consensus. This will be a conference open to as wide a range of participants as possible. The latest version of the typology and toolkit (section 3.2) will be presented and participants invited to discuss, rank and look for gaps.

a. Participants
We will invite participants who have taken part in Child Talk to express an interest in taking part in the national consensus building as we go along. In addition, we will use national advertising to attract early years practitioners, parents, SLTs and commissioners.

b. Methodology
Two copies of the consent forms will be signed at the consensus group by the

participant and a member of the research team, one copy will be retained by the participant and one stored in the study file. The consensus workshop would be expected to take place over a whole day. World café groups will be led by a moderator and supported by facilitators working with the individual groups (all members of the research team). The group discussions will be recorded using a digital audio and video recorder, and supplemented by the research teams field notes. The video recording will be used to disaggregate speakers if difficult from the audio recordings. Outputs will also include notes written on flip charts, post it notes and paper written by the participants during the groups.

3.1.5 Data Analysis

Analysis of ranked statements will be undertaken using quantitative and qualitative techniques. For each, we will first establish the overall ranking of each statement across the entire sample, using measures of central tendency (typically mode and median) and measures of dispersion (standard deviation) to show the judgements of all respondents. Following the first consensus round, a qualitative approach will be used to synthesise statements in order to produce the shorter consensus questionnaire which will be subjected to further quantitative analysis. From this we will identify the top ranking statements for the group as a whole as well as the pattern of responses for subgroups including professionals and service users. We will investigate the main similarities and divergences within and across subgroups. Kendall's W can also be used to assess the level of consensus for each item. The analysis will focus on the generalisability and applicability of the typology as well as identifying priorities for service provision for preschool children with PSLI. In addition, data from Phase 1 of Child Talk – What will provide the level of published evidence that supports the statements. This will result in three different levels of data leading to future research projects:

1) Evidence of effectiveness of interventions and consensus regarding acceptability and/or feasibility (*future evaluation trial of cost effectiveness in SLT services*)

2) Evidence of effectiveness of interventions but no support from practitioners, families or other stakeholders (*future research to identify barriers to use in practice*)

3) Little evidence of effectiveness of interventions but support from practitioners and parents (*future evaluation trial needed*)

3.2 Assessment toolkit

The second work package of Phase II involves the development of an assessment toolkit which will be used to support the use of the intervention framework. This toolkit will enable SLTs to assess environmental and contextual factors related to the child and identify the appropriate intervention to use (individualising therapy). The toolkit will be developed alongside the typology in a series of six steps.

i. **Identify existing published assessment tools**
   A search for existing assessment tools has been undertaken using publisher lists and literature searches. This list will be refined to ensure the assessment tools are valid for the patient group. Further searching will be required as the typology develops and gaps are identified.

ii. **Classify assessment tools in terms of robustness**
   The robustness, validity and reliability of the assessment tools will be identified through literature searching. The assessment tools will be classified

in terms of what they measure and robustness. In addition, at the SLT consensus building groups, we will ask SLTs which assessment tools they use in practice in particular contexts to explore face validity and how this compares to robustness.

iii. Map assessment tools onto typology
As the typology is being iteratively developed through the consensus building groups, the assessment tools will be mapped onto the typology. Therefore the typology that is presented to the later consensus groups will include the assessment tools. This will enable consensus to be sought not just on the interventions being included in the typology, but also on components of the toolkit.

iv. Identify gaps in existing measurement tools
If, and where, gaps have been identified during the mapping exercise, a decision will be made as to whether a short customised assessment can be developed by the research team to fill that gap. This might consist of a few questions to elicit specific information to support SLTs in assessing particular contextual factors. If a more complex assessment tool is required to fill the gap and development work is needed, we will explore routes for obtaining funding to undertake this work as a separate project.

v. Feasibility testing of the assessment toolkit with an SLT service in Bristol
During the development of the typology and toolkit we will undertake some feasibility testing to components of the toolkit in clinical practice. This work is necessary to support the follow on project from Child Talk –What Works, which will be to trail the intervention framework and toolkit in SLT services to determine the effectiveness and cost effectiveness.

vi. Prepare guidance documentation for SLTs
The final step in the development of the assessment toolkit will be to prepare guidance documentation to support the use of the toolkit by SLTs.

3.2.1 Participant Recruitment
The majority of participant involvement in the development of the toolkit will be at the consensus building groups (section 3.1) because the toolkit will be mapped onto the typology and included into consensus discussions. However, SLTs will need to be recruited separately for the feasibility testing.

The inclusion criterion for the feasibility testing is, currently practising SLTs with a caseload that includes preschool children with, or at risk of, PSLI. The Bristol SLT service manager will be asked to distribute an invitation to participate, via email, to staff who meet the inclusion criteria. Staff will be asked to reply to the research team at North Bristol NHS Trust (NBT) via email indicating their interest in taking part in the study.

3.2.2 Methodology
A member of the research team will visit participants who have contacted us to express an interest in taking part to give them an opportunity to discuss the research further and answer any questions they might have. If they are still willing to participate, the selected participants will be given a participant information sheet and a consent form.

Participants would be invited to attend a session with the research team, at which

two copies of the consent forms would be signed by a participant and a member of the research team. One copy will be retained by the research team and one copy given to the participant. At this session, the research team will talk through the assessment tools and how they should be used. The feasibility work will be undertaken with the NHS SLT service in Bristol. Up to five SLTs will be invited to use the assessment toolkit following an assessment clinic with a child with PSLI. The SLTs will use a 'talk aloud' protocol which involves talking through and commenting on how they are using the toolkit into an audio recorder. The SLTs will also be asked to fill in a mini checklist indicating the ease of use of the toolkit, applicability and contribution/value to clinical decision making.

3.2.3 Data Analysis
The audio data from the feasibility testing will be analysed using thematic analysis. In addition a likert scale will be used to determine the ease of use of the toolkit, applicability and contribution/value to clinical decision making. The toolkit will be mapped onto the typology statements generated as part of the consensus exercise.

4. Data Management
All research data will be managed in accordance with the Data Protection Act (1998). NBT will lead the recruitment, data collection and analysis of this phase of the research programme. All original electronic data containing personal identifiable information will be stored in an encrypted folder at NBT following transcription and anonymising by a member of the research team. This encrypted folder will require a password for access. Personal identifiable information will be kept for 10 years in line with NIHR requirements and the files will be tagged with a destruction date. At times data may need to be transferred between sites and files will be password protected and emailed. The transfer of password protected files containing identifiable information between NBT and Manchester Metropolitan University (MMU) will be kept to a minimum. All paper based study related documentation including consent forms will be stored in a locked filing cabinet in the Speech and Language Therapy Research Unit at NBT. Access to the unit is via a key pad.

5. Ethical Considerations
The research programme focuses on interventions for a vulnerable group, that is, young children. All members of the team who will have contact with the children will have Criminal Records Bureau Enhanced Clearance and receive appropriate training in procedures for safeguarding children. In addition we will be working with families for whom communication may be difficult, for whom English is not their first language or is not spoken. Local participation workers and NHS translators will be employed to support effective engagement with these groups. The research programme has collaborators and advisors who are experienced in working with children and adults with communication disability and any new team members will receive appropriate training and support from experienced members. Ethics approvals to undertake this study will also be sought from MMU and University of the West of England (UWE).

6. Expertise on Programme Grant team
The research team, led by Prof. Sue Roulstone and Dr Gaye Powell, will undertake the data collection and analysis. In addition the research programme has co-applicants who will bring their expertise to support the delivery of this research and to advise on methodology, data collection and analysis.

- Dr Julie Marshall (MMU) – National Survey
- Dr Will Hollingworth (UoB) - Health Economics
- Dr Jane Powell (UWE) – Health Economics

- Prof. Tim Peters (UoB) – Statistics/research design
- Mrs Jenny Moultrie (NBT) - Professional lead in Speech and Language Therapy
- Prof. Jane Coad (Cov University) - Engagement of children using art-based methods
- Prof. Norma Daykin (UWE) - Innovative arts methods of data collection
- Prof. Juliet Goldbart (MMU) - Working with parents in diverse settings
- Prof Alan Emond (UoB)- Child health services delivery and evaluations
- Prof Jon Pollock (UWE)- Research design, evaluation and implementation processes
- Dr Gaye Powell (Independent) - Development of measurement tools
- Mr Cres Fernandes (AR Assessment Ltd)- Specialist adviser in psychometrics
- Mrs Linda Lascelles (Afasic) - Support for engaging parents of children

7. Public Patient Involvement (PPI)
Afasic, Supportive Parents and Barnardo's have consulted and collaborated with the PI in developing the grant application, and will continue to collaborate throughout the research programme. In addition the research team have set up public patient involvement to identify the most appropriate method for engaging parents as research subjects and to review all consent forms and participation sheets:

- Two parent research partners attend advisory group meetings to advise on the strategic direction of the research programme.
- A panel of seven parents, who represent families of children with and without communication difficulties, meet every two months to support the development and delivery of strategies to improve parent engagement and recruitment into the study.
- Parents/families/peers from vulnerable/socially excluded communities collaborate in developing strategies and documentation to engage with these communities.

Through the expertise of the PI, research team, programme collaborators and PPI we will ensure that we engage with parents and vulnerable groups in an appropriate manner and that all communication (oral, written) is prepared in language that is relevant to, and appropriate for, the target audiences. The parent information leaflets and consent forms for this study have been developed in collaboration with the parent panel.

8. Dissemination
The findings from this phase of the research project will be disseminated through Conference presentations, (for example the International Association for Logopedics & Phoniatrics, RCSLT biennial conference, national Special Interest Groups) and papers in peer reviewed journals (for example the International Journal of Language and Communication Disorders). Results will also be disseminated through our PPI network.

Outputs from the research programme as a whole will include measurement tools, guidelines, the evidence based typology and a national outcomes framework. The research team will target policy, practice, education for practitioners and public and family awareness when disseminating the findings. As well practitioner journals, peer reviewed articles, the programme will deliver a seminar series that will disseminate the key findings and discuss implementation issues with key stakeholders. At the end of the programme, we will organise a joint stakeholder conference with RCSLT

and AFASIC, (including SLT managers and commissioners) to consider the implications of the programme for possible restructuring of SLT service commissioning and the delivery of SLT services for pre-school children with PSLI.

The outputs from this study will feed into future grant applications, the first of these being to trial the intervention framework and assessment toolkit in SLT services.

9. References

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9) Bercow Report (DCSF 2008) - Review of Services for Children and Young People (0–19) with Speech, Language and Communication Needs http://www.dcsf.gov.uk/slcnaction/bercow-review.shtml

10) Healthy Lives Brighter Futures - The strategy for children and young people's health: DH/DCSF strategy presents the Government's vision for children and young people's health and wellbeing Feb 2009 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_094400

11) Better Communication Action Plan - An action plan to improve services for children and young people with speech, language and communication needs: Dec 2008. Response to Bercow report setting out action plan and initiatives. http://www.education.gov.uk/publications/standard/publicationdetail/page1/DCSF-01062-2008

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Background - Government Policies, consultations, initiatives

Recent government initiatives emphasise the role of communication in a child's health and well-being promoting early identification and intervention to reduce the long term impact on a child's social, education and employment prospects.

Every Child a Talker – (Response to Bercow) Every Child a Talker (ECaT) is a national project to develop the language and communication of children from birth

to four years of age. **Dec 2008**
http://nationalstrategies.standards.dcsf.gov.uk/node/153355

Equity and Excellence: Liberating the NHS (white paper) Sets out the Government's long-term vision for the future of the NHS. **July 2010**
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicy AndGuidance/DH_117353

Frank Field – The Foundation Years; preventing poor children becoming poor adults (independent review on poverty and life chances). Communication and life chances. **Dec 2010**
http://www.frankfield.com/media/press-releases/q/date/2010/12/03/a-new-strategy-to-abolish-child-poverty/

Graeme Allen - Early Intervention: The Next Steps. An independent Review. Readiness for school, readiness for life. **Jan 2011**
 http://www.dwp.gov.uk/docs/early-intervention-next-steps.pdf

Support & Aspiration – A new approach to special educational needs. A consultation. Green paper. **March 2011**
https://www.education.gov.uk/publications/eOrderingDownload/Green-Paper-SEN.pdf

Clare Tickell – The Early Years: Foundations for life, health and learning. Recommendations for EYFS. **March 2011**
http://media.education.gov.uk/MediaFiles/B/1/5/%7BB15EFF0D-A4DF-4294-93A1-1E1B88C13F68%7DTickell%20review.pdf

Sue Roulstone, James Law, Robert Rush, Judy Clegg, Tim Peters. The role of language in children's early educational outcomes. (DoE funded research report) Importance of positive communication environment for children 0-2 years**. June 2011**

10. Supporting Documents
10.1 SLT recruitment advert v.1 17.01.13
10.2 Expert reference group recruitment email (academics) v.1 17.01.13
10.3 Expert reference group recruitment email (phase 1 participants) v.1 17.01.13
10.4 National Perspective recruitment advert v.1 17.01.13
10.5 Consensus exercise PIS v.1 17.01.13
10.6 Consensus exercise consent form v.1 17.01.13
10.7 Parent recruitment flowchart v.1 17.01.13
10.8 Parent recruitment flyer/advert v.1 17.01.13
10.9 Parent invitation letter (NHS) v.1 17.01.13
10.10 Parent verbal information leaflet v.1 17.01.13
10.11 Parent verbal consent form v.1 17.01.13
10.12 Parent information leaflet – groups v.1 17.01.13
10.13 Parent groups consent form v.1 17.01.13
10.14 Parent information leaflet – interview v.1 17.01.13
10.15 Parent interview consent form – v.1 17.01.13
10.16 Feasibility testing PIS v.1 17.01.13
10.17 Feasibility testing consent form v.1 17.01.13