MISLToe SSD WP3 Q&A

This document contains frequently asked questions from PIs of the NHS sites involved in MISLToe SSD WP3. The questions are grouped per topic.

This resource is shared across the ongoing projects in England and Wales. The data collection tools, as well as some aspects of the study protocol, differ between England and Wales. Therefore, some questions and answers may be specific to one of the two countries. In such cases, this will be indicated in brackets. Unless otherwise specified, the information provided applies to both projects.

Note. PIs cannot add questions directly to this document. If you did not find the answer to your question here please contact the team (misltoe@nbt.nhs.uk for England, PCalabrese@cardiffmet.ac.uk for Wales).

The document will be updated periodically.

Taking consent

From the protocol: Parents may give consent over the phone and confirm consent at the routine in-person appointment with the SLT, they may complete an online consent form via an SMS or email link sent to them by the SLT service or they may prefer to complete a hard copy of the consent form to bring with them to the routine in-person appointment, or complete the form with the SLT in the appointment.

See section 7.2 of the protocol

1	**Q**. How does consent over the phone take place? **A.** The PI needs to share the PIS with the parent via email, text, or as a hard copy. The PI will call the parent and take their consent filling in the form on their behalf. The PI will place their own initials in the boxes and make a note at the bottom of the consent form that the parent was not present and that verbal consent was taken.
2	**Q**. How can consent be taken when the PI is not able to meet the family in person and or if parents are not able to edit the word document for tech related issues (e.g., parents do not have access to a laptop)? **A.** In this case the consent needs to be take over the phone (see Q1). The routine SLT (even if not CGP trained) can print and hand out a hard copy of the PIS to parents, so that the PI can take consent over the phone.

Taking consent

3	**Q**. The protocol refers to taking online consent using a link sent via email or SMS. Who can generate this link and how can it be shared? **A.** If this is the preferred method of sharing, site PIs are required to generate the link. This can be done: - By uploading the word document on a secure OneDrive (if the site uses outlook as a platform) and share the link with the parent. Note that for each parent you need to have a separate file stored on your OneDrive. - Create a Microsoft form and share the link with parents. PIs need to create the form themselves by copy and pasting the statements in the consent form provided by the team.
4	**Q**. "Children will also be provided with a PIS appropriate to their age group and will have the option of completing an assent form". Is this optional? In what case is it needed? Is it up to the SLT? **A.** Obtaining assent is optional and is never required for the child's data to be shared if parent consent has been obtained. Approaching the child is at the therapist discretion depending on their clinical judgement related to the child's understanding.
5	**Q**. Do we require a copy of the assent or just consent? **A.** Legally only consent is required, but we would like to be sent both if assent has also been obtained. The consent forms need to be shared by the PI to the study email contact (misltoe@nbt.nhs.uk for England, PCalabrese@cardiffmet.ac.uk for Wales)
6	**Q.** If the routine SLTs other than the PI take consent? **A.** Yes, participants' routine SLTs can take consent, provided that they have reviewed the training slides about GCP principles and discussed them with the PI

MISLToe SSD COS (System One/ Qualtrics)

1	**Q**. What is the difference between number of doses and number of treatment episodes in the questionnaire (10A of intervention section in the questionnaire) (**ONLY ENGLAND**) **A.** This is a repetition, please put the same value in both boxes
2	**Q**. Question number 10 of intervention section in the questionnaire (Who delivered the additional therapy practice activities?) (**ONLY ENGLAND**)

MISLToe SSD COS (System One/ Qualtrics)

	A. Do not select NA as this is the result of bug in the system.
3	**Q Consolidation period:** If the service provided includes a post therapy consolidation period, when do we need to assess for end of EoC? **A.** You should assess the child at the end of the intervention (before the consolidation period) and enter this data as EoC
4	**Q. Multiple EoC:** If, at the end of the intervention, the child receives another EoC, will the assessment from the first EoC also serve as the baseline for the following EoC? **A**. Yes, however the current system will not pull the data automatically so the assessment data needs to be entered again manually.
5	**Q. ICS:** If the child goes to **Welsh medium school** but parents do not speak Welsh, who should fill in the ICS **A**. In this case the ICS should only be completed in English
6	**Q.** Does the **DEAP** have to be completed in **languages other** than English? **A**. No - we would like to capture data from any phonology assessments in any of the child's languages (where this assessment has taken place). If you have completed a phonology assessment in another language (via an interpreter/bilingual SLT, in addition to the DEAP), please calculate the PCC, PVC, PPC from this assessment and add it to the questionnaire.
7	**Q. NAPA** advises Therapists to not go any further through the assessment if a child is struggling with a certain section and to start therapy there. If that is the case, should we follow the guidance and not proceed any further with the assessment and should we put N/A in the boxes of the MISLToe questionnaire for any further sections? **A.** Follow the NAPA manual and stop the assessment when required. For sections not administered leave the field blank (**In Wales)** and type NA **(In England)** and the score if you have. Enter a score of 0 for those instances when the SLT has attempted the test but the child scored 0.
8	**Q. NAPA.** For the "counting words" section, we have had a couple of children who are missing certain grammatical markers or weak information carrying words (i.e. dropping determiners or possessive pronouns from their sentences) so instead of saying the bird is red, the child is repeating the sentence as "bird is red" and then indicating there are 3 words. This is of course incorrect in regard to the target but correct for their realisation. Should we mark this as incorrect, or correct in this context? **A.** This should be counted as correct in this context because we are really focused on whether they can identify word boundaries.

MISLToe SSD COS (System One/ Qualtrics)

9	**Q. Can SLTA's enter into the questionnaire following sessions they have run?** A. Yes, as long as they have access to system one then they should enter the information from the sessions they complete

Other procedural aspects

1	**Q**. The ID number and **PRN** are used interchangeably across documents. Are these the same thing? **A.** Yes they are the same. We will cross check documents moving forward to ensure consistency. Please ensure that PRN is included on the consent form when you store it and **after** you shared the consent with the team.
2	**Q**. **Parent questionnaire** : Some SLTs work within language resource settings, where parents may never attend sessions. In this case parents might not be able to answer some of the questionnaire items (for example, "How long was the assessment session today?") **A.** Parents should complete the questions they are able to answer and leave any questions blank if they do not know the information, rather than avoiding the questionnaire altogether. When required, please instruct parents to specify in the box at the bottom of the survey "I did not attend the assessment because it was completed in school."
3	**Q**. Existing **differential diagnosis**. In the manual, we state: "If a differential diagnosis using the subtypes from the MISLToe-SSD protocol has already been reached, then the diagnostic protocol does not need to be repeated and the clinician can simply enter the COS." However, we have not specified what would be considered acceptable evidence for having already reached that differential diagnosis. **A.** The requirement is that SLTS are using Dodd's subtypes, not that they have completed the diagnostic protocol. So if they are confident then they can go ahead and enter the diagnosis regardless how they achieved it (e.g., assessments different from diagnostic protocol**)**
4	**Q. Inclusion criteria:** Can we include children who have a history of glue ear but no current hearing impairment? **A.** Yes, as long as there the child does not have a hearing impairment they can be included

Other procedural aspects	
5	**Q. Two weeks time limit:** The guidance is to complete assessments within two weeks and enter data within two weeks from completion of assessment. If we cannot meet these timeline what should we do? Should we exclude participants? **A.** At this stage please do not exclude participants based on time constrains, instead note down these challenges and share them during the next focus group.
6	**Q. Multiple interventions.** The system only allows to select one intervention approach per session, what about if we are using multiple intervention approaches? **A.** Please consider whether you are actually delivering two different intervention protocols within the same session, or whether you are using one main intervention approach with a few elements from another protocol to support it. If the latter applies, please select only the main intervention and report the dosage for that approach. If you are genuinely using two intervention approaches, please note that in **Wales** the questionnaire has been updated to allow you to select up to two interventions and record the dosage for both. In **England**, we are unable to make changes to SystemOne at this time; however, we will take this feedback into account and aim to implement it in a future phase of the research
7	**Q. Intervention approach.** The system does not mention the intervention approach I am using **A.** In Wales we have introduced a further option “Other”. In **England**, we are unable to make changes to SystemOne at this time so if you are using an intervention approach that is not among the options, please leave it blank.

Updated guidance from the team:

- For **number of phonemes**, we only calculate consonants, so please ignore the vowel column in the phoneme calculator
- **NAPA**: The COS questionnaire/survey does not require a score for letter-sound knowledge