





# Timing Of Primary Surgery for Cleft Palate NEWSLETTER

December 2012, Issue 7

## TOPS Recruitment Video

Recruitment in TOPS is lower than expected and in any trial it is important to try to understand the reasons for recruitment rate and also to help identify solutions to common issues.

Following a meeting of UK TOPS teams and the development of the document "Top Tips for TOPS recruitment" the team in Manchester developed a video which aims to address some of the key concerns raised by parents.

We would very much like to hear your thoughts on this video and whether or not you think it could be used to help parents decide if they would like to take part. We understand that the current version is aimed at UK centres but would like to explore the possibility of alternative versions if they would be useful.

### The video can be viewed online here:

<https://stream.liv.ac.uk/fgfgaef9>

### Feedback forms are also available online:

For sites in the UK:

<http://www.surveymonkey.com/s/YRGF37M>

For sites in Denmark, Sweden, Norway and Brazil:

<http://www.surveymonkey.com/s/YM3NDF3>

**If you would like to receive a DVD or CD of the video please contact Phil Eyres at the Administrative Centre:**

Email : [phil.eyres@manchester.ac.uk](mailto:phil.eyres@manchester.ac.uk)

## Speech Meeting : Copenhagen

Many of you who are speech therapists will be attending a meeting in Magleås, Denmark on 20-23 January 2013. This is to calibrate and prepare for the 3 year speech recordings, the first of which are expected from our Manchester site in Summer 2013. There will also be feedback and opportunity to discuss the 12 month recordings.

An agenda for the meeting has been sent to all attendees. The meeting will follow a similar structure to the meeting for calibrating the 12 month speech recordings at the same venue in April 2010.

The meeting and venue were excellent and we once again would like to thank Elisabeth Willadsen, Anette Lohmander, Christina Persson and Kathryn Patrick from the Core Speech Group who are currently involved in the preparation and organisation of this meeting.

## Speech Recordings

Many thanks to all speech therapists who have sent practice and trial speech recordings to the Data Coordinating Centre to enable feedback from Elisabeth Willadsen.

Common problems with recordings are:

- the camera being placed too high
- the focus indicates that the camera is too close or too far away.
- Too much background noise

If you have any tips to share which help to correct these problems please let us know.

To ensure good quality of the primary outcome it is important for each team to make one or more practice recordings for the 12 month, 3 year and 5 year assessments.

**If you are having problems making your practice recording please contact Lea Bradshaw at the Data coordinating Centre**  
[tops.trial@liv.ac.uk](mailto:tops.trial@liv.ac.uk)



## Good Clinical Practice

**Free online GCP course by NIHR for UK sites is available at:**

[http://www.crnc.nihr.ac.uk/workforce\\_development/learning\\_and\\_development/gcp/gcp\\_elearning](http://www.crnc.nihr.ac.uk/workforce_development/learning_and_development/gcp/gcp_elearning)

**The access to the course is explained at:**

[http://www.crnc.nihr.ac.uk/workforce\\_development/courses/faqs/GCP\\_elearning\\_FAQ](http://www.crnc.nihr.ac.uk/workforce_development/courses/faqs/GCP_elearning_FAQ)

**Please register at:**

<http://learning.nihr.ac.uk/KIP/Register.aspx>

**Free NIH online course for all Danish, Swedish, Norwegian and Brazilian sites** - Protecting Human Research Participants is available at:

<http://phrp.nihtraining.com/users/login.php>



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## TOPS Frequently asked questions

### Q. When should I withdraw a baby from the trial?

- A. The baby should only be withdrawn from the TOPS trial if the parents have withdrawn consent. Otherwise, once randomised, they should be followed up. Please get in touch with Lea Bradshaw at the Data Coordinating Centre if a baby misses an appointment or there are other reasons for non compliance with the protocol.

### Q. I've used the wrong version of the consent form, what should I do?

- A. As you may know in TOPS we use two consent forms, one for the main trial and one for the Practice speech recordings. They do look similar and it may happen that they get mixed up.

Consent form is an essential document and should be completed in line with Good Clinical Practice and Ethics requirements, so please check that you have used the correct form. Please also ensure that the patient information sheet and consent form itself do not get separated as they are one document.

Once the baby has been randomised and you have added the randomisation number to the consent form, please fax or send a copy to the Data Coordinating Centre as soon as possible. In cases of wrong consent forms being used we will advise you to re-consent on the correct version and to complete a 'note to file' report explaining the reasons for the oversight. If you are not sure or need advice, please get in touch with Lea Bradshaw at the Data Coordinating Centre who is very happy to help.

## Thank You

There have been some changes to the teams in Oslo Bredvedt and Birmingham Children's Hospital.

We would like to thank Lillian Kjøll at Oslo and Rona Slator at Birmingham for their contribution to TOPS as Principal Investigators and for helping in the set up of TOPS and continuing recruitment and assessments.

We would like to welcome Marianne Moe and Patricia Rorison who will be taking on the role of Principal Investigators at Oslo Bredvedt and Birmingham Children's hospital respectively.

Both Marianne and Patricia have been involved in TOPS since site set up and so are very knowledgeable in the TOPS protocol.



## New Data Manager at the DCC

Binyam Tesfaye joined the TOPS team at the Data Coordinating Centre, University of Liverpool in September 2012. He previously had experience of Clinical Data Management at Cancer Research UK, Liverpool Cancer Trials Unit (LCTU).

Binyam will be updating the TOPS database with data received from sites and will coordinate the process of case report form tracking, querying and data entry together with processing speech recordings.



Binyam can be contacted at the Data Coordinating Centre University of Liverpool  
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## Congratulations

Gunvor Semb last week received the 'Paul Herren Award' in Bern.

The Department of Orthodontics and Dentofacial Development, University of Bern, Switzerland, established the Paul Herren Award in memory of its former director Professor Paul Herren. The award is given annually to persons from the orthodontic speciality in recognition of outstanding achievements in teaching, clinical excellence, and orthodontic research.

So, many congratulations to Gunvor!



## TOPS Contact Details

### Main contact at the Data Coordinating Centre

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