



Update: TOPS recruitment workshop

On the 23rd September a TOPS workshop was held to discuss recruitment strategies for UK teams.

This half day workshop took place in Manchester and involved specialist nurses, cleft unit coordinators, site coordinators and speech therapists from the UK teams.

During the workshop participants were asked to consider challenges in TOPS recruitment which were then fed back and discussed. The last half of the day then involved the development of solutions to these challenges and the creation of the document "top tips for TOPS recruitment" which is at the end of this newsletter.

If you have any more top tips that you would like to share please email them to: tops.trial@liv.ac.uk

Based on the positive feedback from the workshop in Manchester we hope to develop future workshops that all TOPS teams can attend.



Update: TOPS trial coordination at the Data Coordinating Centre

As you all know Nicola has moved posts and is now senior trials manager based at the Healing Foundation Centre for UK Cleft Research in Manchester.

The Healing foundation has provided funding for a Clinical Trials Unit that will specialise in cleft and craniofacial research and that will offer support on the development and submission of grant applications, trial coordination and relevant training and education. Nicola is now a member of a core team of 5 staff based at the centre. If you would like more information on the Healing Foundation centre for cleft research please contact cleftcollective@manchester.ac.uk

However, despite the new post it is not quite good bye to TOPS for Nicola. Nicola will continue to provide cover for TOPS at the Data Coordinating Centre until a new Trial Coordinator is in post and will also continue to provide support to the trial and remain an active member of the trial management group.

The TOPS Trial Coordinator post has been advertised within the University of Liverpool with a closing date of the 14th December. If there are no suitable applicants this will then be advertised outside of the university with a closing date in the new year.

The next meeting of the TOPS Trial Steering Committee will be on the 31st January 2012

The next meeting of the Data and Safety Monitoring board will be agreed in the new year.



TOPS Frequently asked questions

We have now been recruiting for 18 months and thought it might be helpful to share with you some of the most frequently asked questions in TOPS:

Q. Should we include babies with Pierre Robin?

- A. Yes babies who have Pierre Robin may be included provided that it is not part of a syndrome, for example, Stickler syndrome.

Q. When should case report forms be sent to the Data Coordinating Centre?

- A. Completed case report forms should be sent to the data coordinating centre within approximately 2 weeks of completion. If you have lots of visits coming up and would prefer to send them in a batch that is fine but please send an email to tops.trial@liv.ac.uk to let us know.

Q. What is the MACRO database?

- A. The MACRO database will be used to store all of the TOPS data electronically. It is nearly finished and is currently undergoing testing. As soon as it is ready for use we will let teams know. For now please send paper case report forms to the Data Coordinating Centre who will clear any data backlog.

Q. When and how should we send consent forms?

- A. Consent forms should be sent to the Data Coordinating Centre by fax as soon as possible after completion unless otherwise agreed.

All consent forms need to be signed by the parent/s and each box initialled. The parents should date the form and then the researcher should also sign and date the form. The original consent form should be kept in the patient notes and copies made for the parents and the site file.

New member of the core speech group

We would like to welcome Kathryn Patrick to the TOPS core speech group.

Kathryn is a speech and language therapist at Manchester Children's Hospital and will be joining Elisabeth Willadsen, Christina Persson and Anette Lohmander on the TOPS core speech group.

As you know, the primary outcome for TOPS is velopharyngeal function at age 5 and how we assess speech in the trial is very important. The core speech group have lots of expertise to share and we are looking forward to the next speech calibration session which is scheduled for January 20-23, 2013.

Practice speech recordings

If your centre is open for recruitment and you have yet to make a practice speech recording for babies aged 12 months please do so as soon as possible.

It is important to send practice recordings in good time before actual 12 month visits so that feedback can be provided.

If you have any questions about the practice recordings or how to transfer them using the encrypted USBs please get in touch.

If you have any queries regarding the TOPS trial or would just like to get in touch please contact a member of the TOPS trial team at the Administrative or Data Coordinating Centre.

TOPS Contact Details

Main Contact Administrative Centre

Dieter Weichart
(Project Manager)

Tel: +44 (0) 161 275 6792

Email:
d.weichart@manchester.ac.uk

Main contact at the Data Coordinating Centre

Nicola Harman
(TOPS cover until further notice)

Tel +44 (0) 151 282 4727

Email:
tops.trial@liv.ac.uk





Timing Of Primary Surgery for Cleft Palate Top Tips for TOPS

Recruitment!

Ideas on how to manage patient preference

- The presentation of the standard timing of surgery is important. Consider completing an audit of surgeries completed at site to find out what the "real" standard timing of surgery is for your centre.
- If the actual timing of surgery varies in your centre consider presenting the standard as between 6 and 12 months.
- TOPS is an international trial and the standard timing of surgery varies across centres and across the globe. Cleft teams achieve good results for both timings of surgery.
- One well-liked aspect of TOPS is that it is unlikely that the date of surgery will be changed unless the baby is unwell.
- Be careful not to assume that parents would prefer surgery at 6 months. So far those who have been randomised to 12 months have been happy with the timing.
- Remember, the TOPS trial is happening because we really do not know which timing is better.

What about maternity leave?

- The length of maternity leave varies but for some it will end when the baby is 12 months old. Have discussions with parents early so that they can talk to their employer about the time off that they might need.
- Explore reality as sometimes due to illness, annual leave etc surgery planned for 9 months can become nearer 12 months.
- Explore how long parents think their child will take to recover from surgery; they might think that it is a lot longer than it actually is.
- Use the 6 week window around surgery to look at when the 6 month and 12 month surgery might be and find a date that is best for both the cleft team and the family.

Burden to parents

- There are lots of appointments for TOPS and some of them, like the speech assessments, can take a long time.
- When scheduling appointments it is important to discuss the needs of each family. For some having as many appointments as possible on one day would be best but others might prefer multiple visits. Offering choice helps the family feel in control.

Take some time for TOPS

Consider adding TOPS to the agenda of your team meetings to regularly discuss progress and any challenges. It is helpful to keep everyone up to date especially if the team is split up across different locations. Regular team meetings might also help the continuity of information given to families.

Presenting TOPS information

- Be sensitive to the needs of each family consider each one on a case by case basis so that the timing and style of delivery best suits them. Consider background, culture etc
- You don't have to give all of the TOPS information at once. It's ok to let the parents know that you will talk about something the next time you see them. Of course, some families might want all of the information in one go and that is ok too.
- The word "trial" can raise all sorts of concerns because parents think it means that their child will be practiced on. Consider using the word "trial" at later visits when the parents have had time to adjust and to take in other information.
- If asked at what age the surgery will be carried out consider initially presenting the broader time span of 6 months – 1 year. At this stage parents often need reassurance that the palate can be closed rather than a specific time.
- Ensure that all team members are presenting the information similarly allowing continuity and reinforcement of information.

Communication is key!



Good communication between the team will help recruitment and present a unified front. Good communication with the family not only ensures that they have all of the information they need about TOPS but that they are happy to raise queries and talk through solutions.

Future developments

- Consideration will be given to offer incentives to both parents and children.
- Retaining enthusiasm and retention is important. Future workshops to develop further TOPS TIPS will be arranged.
- Please remember to share your ideas and concerns with the trial managers in order that they can be shared between all teams.

