



## NATTINA Programme Meeting 27<sup>th</sup> April 2018

We would like to thank everyone who attended and contributed to the successful NATTINA Programme Meeting. It was great to have so many sites attending and sharing their knowledge:

**NATTINA Recruitment** is due to close on 30/04/2018. It has been a combined effort across a huge number of sites – each contribution is very valuable. Oxford was congratulated: although one of the later sites to come on board, the team managed to recruit 20 participants. The sites represented at the Programme Meeting reflected on positive recruitment strategies. Posting out a PIS to potential participants worked well, as patients had already heard of the study before attending clinic. Dedicated NATTINA clinic time also boosted recruitment. The PI in Glasgow – a high flying recruitment site - commented that all their potential participants also watched the NATTINA video.

Patient preference has strongly influenced NATTINA recruitment. The SIGN guidance is currently used in primary care to determine patient eligibility for tonsillectomy. Patients know this and thus arrived in clinics anticipating being listed for surgery, and not interested in pathways which might delay it. The Chief Investigator (CI), Janet Wilson, noted that work needs to be done regarding patient preference in relation to tonsillectomy referral rates as evidence suggests many go well beyond the SIGN qualifying threshold before referral.

**Screening and Data Findings** – The NCTU team look forward to assessing how each site approached participants when we collate the final screening logs. The Glasgow site staff have already reviewed their screening data, comparing the demographics of those recruited v those not recruited (see also the presentation by Prof MacKenzie). The Aberdeen group are exploring the development of a Tonsillectomy Decision Aid

### Important GDPR Updates from 25<sup>th</sup> May 2018.

- NCTU will set up nhs.net accounts for contact details forms and for SAE reporting.
- Sites must send documentation from an nhs.net account to the NCTU nhs.net account
- If sites cannot send from an nhs.net account the email must be encrypted (or continue to send by fax).
- Meanwhile **continue to use the SOHO66 fax numbers:**
  - Confidential participant info 0191 580 5006
  - SAE Reports 0191 580 1106
- NCTU will keep sites updated about any further, central HRA guidance.

**MACRO Update** – how to remove orange missing data signs within MACRO, for data that is genuinely not available, was covered in the presentation – see upload. To remove the orange symbol, right click on it, select 'change status' and then select 'not available'. The withdrawal form in MACRO was also discussed and sites advised that this page may need a little updating so for the time being - only complete it for participants who are a genuine withdrawal.

As we move into follow up, NCTU will raise with sites any MACRO Data Clarification Requests (DCRs) - small red flags on questions or forms. Site staff delegated on the study delegation log to carry out data query resolution should within 2 weeks:

- amend/edit data, AND
- respond to the DCR (to advise NCTU of the action taken)

It was how queried NATTINA captures what happens to participant after the study i.e. has a participant randomised to the conservative treatment arm now been referred for surgery. This information is captured within the 24 month MACRO follow-up form.

**NATTINA Follow-up is all important now.**

**Hard won recruits who do not complete 12 and 24 months FU do not contribute to the trial outcomes and power.**

It was agreed NCTU will provide each site with an optional tracker to facilitate scheduling of follow-up appointments. A central NCTU tracker will generate reminders when a participant follow-up is due.

Sites observed that those randomised to the conservative treatment arm tend to attend in person more readily than the surgery cohort. Every effort should be made to maximise face to face follow-up. If efforts fail, sites can post questionnaires including a stamped addressed return envelope. Nonsurgical patients should also be phoned to assess willingness to remain in the deferred group.

Once a participant has attended a 24 month visit, it is helpful if sites inform NCTU, who then terminate weekly texts.

**STAR system update** – main issue concerns text messages. A change in the server chain somewhere along the way can result in failed message receipt. A problem if a participant is responding but we are not receiving this response. Although infrequent, all primary outcome data are precious – might future studies use platforms such as WhatsApp?

For NATTINA, when NCTU spot any new non-responders on the non-responders list from the CI Data – the company managing the STAR system, NCTU will contact sites to explore possible reasons - the sooner this can be resolved the better to limit data attrition.

**Steroids for Tonsillitis?** – When the NATTINA application was first drafted, it was envisaged that there would be 3 arms – surgery v conservative treatment v rapid access to treatment with antibiotics and steroids. The funder however supported just 2 arms – surgery v conservative treatment. As part of this programme meeting, Professor Kim Ah-See, PI at the Aberdeen site, gave a presentation on how the evidence regarding steroid use in tonsillitis has progressed during the life of NATTINA. The three key publications which informed his presentation are:

- Hayward et al. *JAMA* **2017**;317(15):1535-1543. doi: [10.1001/jama.2017.3417](https://doi.org/10.1001/jama.2017.3417)
- Aertgeerts et al. *BMJ* **2017**;358:j4090. doi: [10.1136/bmj.j4090](https://doi.org/10.1136/bmj.j4090)
- Sadeghirad et al. *BMJ* **2017**;358:j3887. doi: [10.1136/bmj.j3887](https://doi.org/10.1136/bmj.j3887)

**Feedback Session –**

A major NATTINA learning point was that more engagement with GPs/Primary Care would have been beneficial. A GP who feels a participant meets the SIGN guidelines will refer on for tonsillectomy. Such patients attend clinic expecting to be listed for surgery. At this early stage, it would have been preferable if GPs advised patients that they were being referred for a specialist opinion in respect of their recurrent sore throats.

The Primary Care Research Network is a route to access GPs – the Bradford site has experience of presenting studies in this forum which involves many GPs.

Currently, crossover and withdrawal do not appear to be key NATTINA issues.

### **NCTU Actions**

- upload example of STARlet questionnaire to website
- capture information regarding how sites approached potential participants
- review MACRO withdrawal form usage and update sites (above)
- check 24 month follow up form in MACRO
- provide sites with follow-up tracker
- complete central tracker and alert sites when a participant follow-up is due
- continue update bulletins to sites during follow up would be useful

### **Attendees**

Janet Wilson – Chief Investigator

Nicola Goudie – Trial Manager

Faye Wolstenhulme – Trial Manager

Julia Philipson – Clinical Trial Administrator

Janet Jobling – Project Secretary

Ken MacKenzie – Principal Investigator, Glasgow

Paul Sergeant – CI Data

Sara Jarvis – Principal Investigator, Cumbria

Janet McGowan – Research Nurse, Bradford

Melissa Hawkes-Blackburn – Research Nurse, Frimley Park

Abigail Tetteh, Research Nurse, Guy's Hospital

Kim Ah-See – Principal Investigator, Aberdeen