



TIMING OF STOMA CLOSURE IN NEONATES

PARENTAL ADVISORY GROUP MEETING

MONDAY 8TH JUNE 2020

MINUTES

Attendees: Nigel Hall (Study PPI lead), Lucy Flanagan (Study PPI representative); 7 parents who had registered to contribute to the parental advisory group

Meeting was held using the Zoom platform and lasted 2 hours, attendees had been sent the parent information sheets and interview topic guides in advance of the meeting.

1. **All attendees introduced themselves** and their experience of having a baby with a stoma

2. **NH introduced the study and what the PAG was all about**, including that the current study is a feasibility study to find out *if* a future bigger trial will actually be possible, and that the purpose of the PAG is to help the study team in making sure that the study is designed in such a way that is likely to be acceptable as possible to parents who we will be asking to participate.

3. **HOW AND WHEN TO APPROACH PARENTS ABOUT TAKING PART IN TOSCIN**
 - Detailed discussion and appreciation that this was an important to consider.

 - a) **WHEN to approach**
 - the group identified there may be a difference between preterm and term babies:
 - preterm babies may be critically unwell during the time that they need a stoma (e.g. NEC or SIP) but that their parents have already come to terms with the fact that they have a preterm baby who may have a stormy course.
 - for term babies, often the problem has not been known about before birth and the parents said they were a complete mess just learning about the diagnosis.
 - Further some Mum's may have had Caesarian section and have medical needs of their own.

 - **Consensus ADVICE regarding WHEN to approach:**
 - AFTER baby has recovered from being critically unwell
 - Once parents have had time to come to terms with the fact that their baby has a stoma

- Once mother is well enough to enter a discussion about research
- Definitely prior to discharge home

b) WHO should approach the parents

- Someone who the parents know and have some form of relationship / trust with
- NOT a research nurse who has never met the parents before (some parents actually reported deliberately avoiding research nurses as they felt they were being hounded about research projects)
- The surgeon / surgical CNS would be an ideal person to introduce the study even if they then passed further discussion on to another person

c) HOW should parents be approached

- Ideally at the bedside – parents don't want to be dragged away from their baby to talk about research
- In an informal and relaxed way as possible
- In a way that emphasises first what the impact on their baby and them will be – e.g. emphasising early on that *'this will not mean any extra tests or procedures for your baby'*
- A discussion should take place first then written information should be given (almost *'as a record of our conversation'*)

d) ADJUNCTS for recruitment

- Some units have a parents' forum and it was suggested that research projects could be discussed in this so that parents were aware of research taking place in that unit
- Most units have a parents' coffee room and it was suggested that it would be helpful to make a poster about the study for units to put up in the coffee room which parents may read. If their baby then went on to need a stoma they may have already had some knowledge about the study

4. THE INFORMATION SHEETS

- The information sheet for babies and parents was discussed but recommendations are valid for both this and the PIS for interviews only
- The group liked the use of bullet points but felt that starting the sheet with bullet points seemed a bit officious
- They suggested the sheet should start with a brief section on why the research was being done
- The keypoints section should emphasise the following:
 - i. reassurance that the research would not involve anything extra for their baby (no additional handling, no additional tests etc)
 - ii. just need parent engagement, nothing more
 - iii. the anticipated time commitment and over how long
 - iv. that they would not be taken away from their baby for the purposes of the research
 - v. reassurance that if they say yes and change their mind later that is OK
- The *'Who can take part?'* section should be replaced with a sentence saying 'we have asked you to take part because..... Doesn't need a section of its own since it is obvious!
- The *'What does the study involve?'* section could be turned into summary bullet points – what do we need from you and your baby?
- The contact section felt very impersonal – they want local people only – they don't care who the national leads are or who the NPEU is – if they have a problem they will talk to someone locally who they trust.
- It was recommended that after giving a printed copy to parents it would be a good idea to email them a copy as well – many parents said they left pieces of paper lying all over the place whilst their baby was on NICU!

- The group suggested that having a study webpage would be a good idea to act as a further source of information and perhaps include a blog for parents to add comments or report their experiences of being involved.
- The group felt there was nothing 'missing' from the sheets

5. THE INTERVIEW TOPIC GUIDES

The group discussed the questions and had some thoughts on additional questions based on their experiences. It may be that these questions are not all helpful in relation to the purpose of the interviews but they are included nonetheless.

Section 1

- 1.1 Why are age, occupation etc in 1.1 being collected at all? If these are needed please do them at the end and justify why they are needed. Having them at the beginning is annoying and detracts from the main purpose of the interview – get to the meat ASAP.
- 1.2 (Hospital sample) Can these be pre-populated from clinical information if the baby is also involved in the study so that the parents don't have to go through it all again?

(Social media sample) Do you recall any specific reason why the stoma was closed when it was? Do you recall if all the doctors looking after your baby agreed about this or if there was any disagreement? If so, how did you feel about this?

For social media sample (i.e. likely babies who have had their stoma closed) there were some other thoughts about things that may impact timing (not all may be relevant for the interview):

- Availability of theatre space / specialist equipment / specialist surgeon
- Did you agree with the timing at which the stoma was closed?
- Did your acceptance of the stoma have any impact on the timings at which it was closed? *But perhaps this opens up parental acceptance being a potential outcome measure?*

Section 4

The group really struggled to understand this section (in NHs experience this is common when trying to have discussions about outcome measures).

Regarding asking about outcomes:

- Parents just want their baby to be healthy
- Talking about the timing of stoma closure in relation to this added confusion.
- When trying to elicit outcomes some other phrases may be helpful - perhaps 'What things are important to you?', 'What things had an impact on you and your baby -emotional and physical?' 'What things do you think we should measure?'
- Need to recognise that for some conditions the longer term (functional) outcome may be most important – therefore timing may not matter at all.



TIMING OF STOMA CLOSURE IN NEONATES

PARENTAL ADVISORY GROUP MEETING

MONDAY 7TH DECEMBER 2020

MINUTES

Attendees: Nigel Hall (Study PPI lead), Lucy Flanagan (Study PPI representative); 5 parents who had registered to contribute to the parental advisory group

Meeting was held using the Zoom platform and lasted 2 hours, attendees had been sent the draft RCT parent information sheet in advance of the meeting.

1. **All attendees introduced themselves** and their experience of having a baby with a stoma
There was one parent who had not attended the previous PAG meeting
2. **NH reminded the group about the study and what the PAG was all about**, including that the current study is a feasibility study to find out *if* a future bigger trial will actually be possible, and that the purpose of the PAG is to help the study team in making sure that the study is designed in such a way that is likely to be acceptable as possible to parents who we will be asking to participate.
3. **NH updated the group about progress in the study thus far**, including the fact that COVID has resulted in some delay to the overall anticipated timeline but that the study has managed to continue, albeit at a slower pace than planned. There has been a survey of clinicians and NH gave the group an overview of the findings of this.

4. **DISCUSSION ABOUT OUTCOMES**

The group discussed possible outcomes that the study may wish to measure as part of the proposed RCT if it is feasible. NH explained to the group that deciding which outcomes to measure is a really important aspect of a RCT and is often difficult to reach consensus on which ones to measure. The group then held a discussion about which outcomes they felt were important to measure in a trial that would investigate timing of stoma closure. The following outcomes were raised by the PAG, listed in order of highest priority to the group:

1. A general parental view of their child's health status
2. Weight gain
3. Advancement of feeds / duration of PN
4. Stooling pattern
5. General development

6. Length of stay in hospital
7. Problems with stoma
8. Healing / surgical complications
9. Respiratory support

An additional aspect of measuring outcomes that was raised is that different outcomes become relevant at different points in time. As an example it was recognised that “development” is something that becomes important over a longer period of time; “stooling pattern” is another outcome for which the longer term outcome is relevant rather than in the short term.

NH shared with the group the outcomes that had been prioritised in the clinician survey. It was noted that there was some overlap between the clinician and PAG priorities but equally some differences. NH explained that this is one of the several reasons that it is so important to ask all relevant stakeholder groups about which outcomes should be measured in research.

5. PROPOSED DRAFT RCT PARENT INFORMATION SHEET

The group had been sent this to consider in advance of the meeting. The PIS was dissected in some detail and recommendations made regarding how it could be revised to improve readability, engagement and understanding. These covered the format of the document as a whole (leaflet vs A4 sheet), content, wording and other aspects. A few key points were made:

- Pamphlet style is more acceptable and easier to manage than A4 sheet
- There was lots of information on the sheet with a fair amount of repetition
- Much of the text was long winded and could be made shorter and more simple
- The Q&A format was liked as a general rule
- The key points section was helpful but too long and only useful if the same information is not repeated later on in so much detail
- The governance information could easily be added to a website for parents to access if they wish (e.g. GDPR but also ethics, governance, funding etc.

On the basis of this discussion it was agreed that NH would create a new draft of the PIS and members of the PAG kindly agreed to review this revised version and amend it as necessary.

6. NEXT STEPS FOR PAG

NH outlined the next stages of the feasibility study to the group including that the clinical study will hopefully start in the Spring of 2021 and run for about 9 months. Workstream 3 is progressing and will run in parallel to that. It is anticipated that there will be limited requirement for further input from the PAG into the design and delivery of the feasibility study but all members were keen to offer their input should it be necessary. Equally the PAG were keen to learn about the progress of the study and also the findings. A further meeting of the PAG is planned for later in 2021.



TIMING OF STOMA CLOSURE IN NEONATES

PARENTAL ADVISORY GROUP MEETING

24th NOVEMBER 2021

MINUTES

Attendees: Nigel Hall (Study PPI lead), Lucy Flanagan (Study PPI representative); 4 parents who had registered to contribute to the parental advisory group

Meeting was held using the Zoom platform and lasted 1 hour.

1. **All attendees introduced themselves.** All parents had previously joined at least of the previous PAG meetings
2. **NH reminded the group about the study and what the PAG was all about**, including that the current study is a feasibility study to find out *if* a future bigger trial will actually be possible, and that the purpose of the PAG is to help the study team in making sure that the study is designed in such a way that is likely to be acceptable as possible to parents who we will be asking to participate.
3. **NH updated the group about progress in the study thus far**, including the fact the majority of the work has now been completed and the analysis stage of the study is getting well underway. Once all the data have come in then the group are planning a meeting called a *consensus meeting* to discuss the key findings of the work and this will be the final stage of this ToSCiN study.

4. **CONSENSUS MEETING**

NH explained that once all the workstreams have been completed, there will be a meeting to which many different stakeholders will be invited to attend. The purpose of this meeting will be to have a discussion about the findings of all the different bits of work completed. The study team will also try to get some form of agreement to understand if running a future trial will actually be feasible or not, and if it is felt to be feasible to have a discussion about the best design a future trial. It will be really important to have parent representatives at that meeting since we want to make sure that the views of parents are both listened to and included in the decision-making. It would also be particularly helpful to have members of the advisory group there since they have a really good understanding of what the study has been about so far. Several members of the advisory group indicated that they would be interested in being part of those discussions.

5. NEXT STEPS FOR PAG

At the end of the study it would be really helpful for this group to meet one final time and discuss what the study has found and consider possible plans for a future trial. It would also be really great to have the groups thoughts about how to best disseminate the findings of the study and in particular making sure that this is done in a way that the findings are accessible and meaningful to other parents in future. It is likely this will be towards the end of 2022 or perhaps early in 2023.