



Non-invasive ventilation in the management of children with bronchiolitis: A feasibility study

NOVEMBR Study Parent/Legal Representative Information Sheet: Phase 2 Delphi Survey

1) Why are we doing the NOVEMBR study: Phase 2 Delphi survey?

Bronchiolitis is a common, viral, chest infection that affects babies and young children up to 2 years of age. Bronchiolitis usually occurs during the winter months (October – March). A small number of children with bronchiolitis (around 3 out of every 100) need to come into hospital for help with their breathing or feeding.

When children with bronchiolitis have breathing difficulties they are often given oxygen in hospital. Oxygen can be given in a number of different ways, including through a face mask, head box or nasal cannula. We want your help to design a study to assess which way of giving oxygen works best.

Up until now, studies have used different ways of measuring the effects of treatment. This makes comparing the results of trials very difficult. The aim of this study is to agree a 'core outcome set'. This is a list of outcomes that all trials in bronchiolitis should measure and report. Having a core outcome set will help to make sure that the results from all trials can be combined to get a better understanding of which treatments are best.

It is important that the outcomes included in a core set are relevant to everyone looking after children with bronchiolitis. We are therefore asking health care professionals and parents/legal representatives to take part in a special type of survey, called a Delphi survey. The results of this survey will show us which outcomes both health care professionals and parents/legal representatives agree are most important and should be included in the core outcome set.

2) Why have I been asked to take part?

We are inviting you to take part in this survey because your child has been recently been diagnosed with bronchiolitis.

3) What will I have to do if I take part?

You will be asked to fill in an online survey where you rate the importance of a series of outcomes on a scale of 1 to 9 (low importance to extremely high importance). Once all participants have completed the survey, you will be asked to complete the same survey again. You will be shown the scores given to each item by other people completing the survey and you will be given the option to either leave your scores the same or change them.

Important things you need to know about the Delphi Survey if you decide to take part:

- ❖ You will be asked to complete two online surveys.
- ❖ Each survey will take approximately 15-20 minutes to complete
- ❖ The survey will ask you rate on a scale the importance of a number of different outcomes.

4) What are the possible disadvantages of taking part?

Completing the survey will take between 15 -20 minutes, although it doesn't have to be done in a single sitting – you can complete it in part and come back to it later. We will send you e-mail reminders to complete the survey.

5) What are the possible benefits of taking part?

By taking part in this study, you will help us to make sure that the outcomes we include in the core set are relevant to healthcare professionals, children with bronchiolitis and their families. Participants who complete **both** rounds of the survey will be entered into a prize draw to win an iPad. Additionally, all participants will be provided with a certificate on completion of the survey.

6) Will my taking part in this study be confidential?

You will be asked to provide details including your name and e-mail address when you register to take part. This information will be kept securely and will not be accessible to anyone outside the research team. We will never pass on your personal information to anyone else. Your responses and all the survey results will be stored anonymously so nobody except the immediate research team will know your individual answers.

The only other time someone might need to look at the study information is during an audit or monitoring visit. If you agree, they will include your identifiable data when doing the checks (they will see it belongs to you). Anyone that does look at the data will have a duty to keep it confidential.

7) Do I have to take part?

Taking part is completely voluntary. If you decide to take part then later change your mind, you can withdraw at any time without giving your reasons. If you wish to withdraw, simply contact us (contact details below) and tell us you wish to withdraw from the study and we will not send you any more e-mail reminders. If you withdraw you can also request that we do not use any of the responses you have given so far, in which case all the responses you have given to the survey will be deleted.

8) What will happen to the results of the NOVEMBR study?

The results of the study will be shared in reports and scientific journals. A copy of the findings will be made available via the NOVEMBR study website.

After completion of the Delphi survey, a consensus meeting will be held by the NOVEMBR study team for all participants of the Delphi. If you would like to be invited to this and/or an end of study event towards the end of the NOVEMBR study, please provide your contact details on the acknowledgement page at the end of the Delphi survey.

9) Who is involved in the NOVEMBR study?

Alder Hey Children's NHS Foundation Trust is responsible for managing the NOVEMBR study; they have asked that the day to day running of the study is carried out by the Clinical Trials Research Centre (CTRC), part of the Liverpool Clinical Trials Collaborative at the University of Liverpool.

The National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) is funding the study.

This study has been reviewed by expert members from the funding body and by the local Research Ethics Committee who have given approval for the study to take place. The Delphi system will be archived for a year and then deleted along with the data stored in the system.

10) What if there is a problem?

If you have a concern about any aspect of this study, you should speak to Clare van Miert initially who will do her best to answer your questions. If you remain unhappy and wish to complain formally, then you should contact:

Patient Advice Liaison Service (PALS)
PALS, Alder Hey Children's NHS Foundation Trust, Eaton Road, Liverpool L12 2AP
Email: pals@alderhey.nhs.uk
Telephone: 0151 252 5374 or 0151 252 5161

11) How to contact us

If you have any questions and/or would like to take part with the Delphi survey please contact:

Lead Investigator – Dr Clare van Miert
Telephone: 0151 252 5573
Email: aslcvmliv.ac.uk / clare.vanmiert@alderhey.nhs.uk

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