

6 MONTH POST RANDOMISATION FOLLOW-UP

CONFIDENTIAL

Study number	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Infant initials	<input type="text"/>	<input type="text"/>	<input type="text"/>		

Name of nurse completing this questionnaire	<input type="text"/> <i>please print name</i>					
Signed	<input type="text"/>					
Date	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Notes for completing this form

Explanatory text and instructions for completion of the questions are in italics in a separate box before each set of questions. All questions in the grey boxes should be completed. Unless stated otherwise, please complete all questions on the form. In certain circumstances some questions may not be applicable and where this is this case, there are instructions on exactly what information may be missed.

Please complete the information in the required format (as specified in the form). For questions with a Yes/No answer, please mark the relevant Yes/No box with a 'X' (i.e. if the answer to a question is 'yes', the yes box should be crossed and the no box should be left blank).

Before asking the following questions please ask the parent/carer if there has been any change in circumstances since you last spoke, in particular please check that the arrangements for childcare and employment status of parent/carers remain the same. If anything has changed in relation to the questions to be asked, please mark on the form where and adjust the questions appropriately (for example, if mother has now returned to work and child attends childcare, please ask for details of number of hours child has missed from normal childcare etc).

1. Resolution of cough

Before asking the questions below please refer back to the answers given to these questions during the day 28 follow-up visit. If the cough had stopped and parent/carer felt that the child was back to normal by day 28 please do not ask these questions and score through this section. If the cough was still present and the parent/carer did not feel that the child was back to normal please ask both questions. The resolution of cough guidance sheet should be used to help the parent/carer answer the questions and provide accurate dates.

Has your child stopped coughing?

 Y N

Date cough stopped

D	D	M	M	Y	Y
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Do you feel that your child is 'back to normal'?

 Y N

Date back to normal

D	D	M	M	Y	Y
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Please remember to record any adverse events (AEs) and serious adverse events (SAEs) when asking how the child has been feeling since discharge. AEs should be recorded on the BIDS AE log. Any AEs that meet the criteria for 'serious' identified at the 6 month follow-up call DO NOT need to be reported as SAEs, regardless of when they occurred.

2. Healthcare utilisation

Please ask if the child has seen a doctor since the last follow-up. All visits to see a doctor should be recorded, even those visits that were for symptoms not related to this episode of bronchiolitis.

Have you taken your child to see a doctor since the last follow-up?

 Y N

If yes, please complete the details below

How many visits to GP

How many visits to hospital (OPD)

How many visits to see A&E

If admitted to hospital, how many nights? (admission means overnight stay)

If the child was taken to the doctor, please ask the parent to give an estimate of the total travel expenses incurred. If the parent is unsure, please encourage them to guess by prompting on the mode of travel and average cost of journey (for example, if they travelled by bus ask them how much a bus fare is etc)

Estimate of costs (total costs if multiple visits)

£

3. Bronchiolitis outcomes

Please ask the parent/carer the following questions on how they feel the child's chest has been since their admission with bronchiolitis. These questions should be asked even if the parent has not had to take the child to see a doctor. These questions are asking how the parents/carers perceive their own child's health has been and is not necessarily linked to visits to the doctor.

Do you consider that your child is more likely than other children his/her age to have a bad chest following his/her bronchiolitis (the episode resulting in admission and recruitment into BIDS)? Y N

How many times has your child had a bad chest since his/her bronchiolitis (the episode resulting in admission to hospital and recruitment into BIDS)?
If parents are unsure, please encourage them to give an estimate

Have you had to get antibiotics for your child since his/her bronchiolitis (the episode resulting in admission and recruitment into BIDS)? Y N

If yes, how many times have you had to get antibiotics
If parents are unsure, please encourage them to give an estimate

4. Time off work and missed activities

Please refer back to question 7 in the admission questionnaire (occupational status of parents/lead carers) before asking the following questions. The questions below should be asked for each parent/carer, if one parent/carer is absent (identified from the admission questionnaire) please score through relevant table and mark as NK.

Mother/lead carer

From the admission questionnaire, is the Mother/lead carer employed? Y N

If yes, please ask questions 1 AND 2. If no, please ask only question 2 and score through question 1.

1. Have you had to take any time off work since the last follow-up call to look after your child? Y N

If yes, how many hours have they taken off work? hours

2. Have you had to miss any of your normal activities since the last follow-up to look after your child? (normal activities include shopping, meeting friends, exercising) Y N

If yes, how many hours have they missed? hours

Father/second carer

From the admission questionnaire, is the Father/second carer employed? Y N

If yes, please ask questions 1 AND 2. If no, please ask only question 2 and score through question 1.

1. Has your husband/wife/partner (or other) had to take any time off work since the last follow-up call to look after your child? Y N

If yes, how many hours have they taken off work? hours

continued on next page

2. Has your husband/wife/partner (other) had to miss any of their normal activities since the last follow-up to look after your child? (*normal activities include shopping, meeting friends, exercising*)

If yes, how many hours have they missed?

 hours

5. Childcare

Please refer back to question 9 in the admission questionnaire (childcare) before asking the following questions. The following questions should only be asked if the child normally attends paid or unpaid childcare.

From the admission questionnaire, does the child regularly attend paid or unpaid childcare?

If yes, please ask the following. If NO, please score through the following questions

Has the child been well enough since the last follow-up call to attend normal childcare?

If no, how many hours the child has missed?

 hours

6. Anxiety questions

The following section is a series of standard questions to measure anxiety levels of the person answering the questions. Before asking these questions please explain to the parent/carer the type of questions that will be asked and the reasons that they are being asked. The following points should be used as a guide for the information given to the parent/carer.

Please make the parent/carer aware of the following:

- These questions are being asked as part of the study only. These questions are not being asked because of their child's illness or treatment, their behaviour or actions
- All answers given will be kept confidential but will be collated and anonymised as part of the study analysis
- There is no 'correct answer', parents/carers should answer honestly and be reassured that the answers will not be recorded in the medical notes, or be made available to their doctor
- The purpose of these questions is to measure if parents (in a general way) are anxious when their child is admitted with bronchiolitis, and to see if/how this anxiety changes over time (up to the 6 months)
- When answering the questions the parent/carer should give their immediate response and should be based on how they feel at that particular moment, rather than spending a long time thinking about their answer

If you are concerned or worried by the responses to the following questions please make the ward nurses and/or the BIDS PI aware of this. Please record this in the BIDS ISF by completing a file note describing the actions taken and any follow-up required.

continued on the next page

I feel tense or 'wound up'

1. Most of the time

2. A lot of the time

3. From time to time, occasionally

4. Not at all

I get a sort of frightened feeling as if something awful is about to happen

1. Very definitely and quite badly

2. Yes, but not too badly

3. A little, but it doesn't worry me

4. Not at all

I can sit at ease and feel relaxed

1. Definitely

2. Usually

3. Not often

4. Not at all

Worrying thoughts go through my mind

1. A great deal of the time

2. A lot of the time

3. Not too often

4. Very little

I get a sort of frightened feeling like 'butterflies' in the stomach

1. Not at all

2. Occasionally

3. Quite often

4. Very often

I feel restless as if I have to be on the move

1. Very much indeed

2. Quite a lot

3. Not very much

4. Not at all

I get sudden feelings of panic

1. Very often indeed

2. Quite often

3. Not very often

4. Not at all

Please photocopy the completed form and send the copy back to:

Fiona Sloan
BIDS Trial Manager
Edinburgh Clinical Trials Unit (ECTU)
OPD 2, 2nd Floor
Western General Hospital
Crewe Road South
Edinburgh
EH4 2XU

Tel: 0131 537 2516

The original questionnaire should be retained in the BIDS participant file

To be completed by ECTU only

Data entered by (initials)

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Date

D	D	M	M	Y	Y
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