

BIDS

Bronchiolitis of Infancy Discharge Study



DAY 7 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" value="D"/>	<input type="text" value="D"/>	<input type="text" value="M"/>	<input type="text" value="M"/>	<input type="text" value="Y"/>	<input type="text" value="Y"/>

Has the child been discharged from hospital?

If yes, please complete ALL sections of the questionnaire. If no, please only ask the questions in section 1, 3, 4 and 6. Questions 2 and 5 should be scored through on the form before sending back to ECTU.

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 the 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).

1. Resolution of cough

Please ask the parent/carer the following questions to find out about the child's cough. Severity of cough will be variable and parent defined. Please help the parent answer the following questions by using the resolution of cough guidance sheet. If cough has resolved, please ask for the date. If cough has not resolved yet, please mark as no, remind parents that you will be asking about this again in 7 days and suggest they record date cough stopped in advance of next follow-up.

Has your child stopped coughing?

 Y N

Date cough stopped

 D D M M Y Y

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

 Y N

Date back to normal

 D D M M Y Y

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' should be recorded on the BIDS SAE form and faxed to ECTU (refer to protocol section 11 for guidance)

2. Healthcare utilisation

Please ask if the child has seen a doctor since discharge. 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 discharge?

 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 child admitted, please complete a BIDS SAE form and fax to ECTU on 0131 537 3851

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. 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

continued on next page

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 discharge 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 discharge 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 discharge call to look after your child? Y N

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

2. Has your husband/wife/partner (other) had to miss any of their normal activities since discharge to look after your child? (*normal activities include shopping, meeting friends, exercising*) Y N

If yes, how many hours have they missed? hours

4. 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? Y N

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

Has the child been well enough since discharge to attend normal childcare? Y N

If no, how many hours has the child has missed? hours

5. Medications

Please ask the parent/carer if they have had to get any extra medications for the child since discharge. Extra medications mean any additional medications that were not prescribed to the child during the hospital admission. Please record only the details for medications that were prescribed or purchased after discharge. Please do not record details of any medications that are being given to the child from a supply that the parent/carer already had (i.e. they have not bought or been prescribed the medication after the child was discharged). Please complete all dates where possible. Where part of the date is not known, please mark as NK and complete the rest of the date field.

Have you had to get any extra medications for your child since the last follow-up?

 Y

 N

If yes, please complete details below

Medication name	Indication	Prescription		Over-the counter medication		Start date	Continuing?		End date (if not continuing)
<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="text"/> D <input type="text"/> D <input type="text"/> M <input type="text"/> M <input type="text"/> Y <input type="text"/> Y	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="text"/> D <input type="text"/> D <input type="text"/> M <input type="text"/> M <input type="text"/> Y <input type="text"/> Y
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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.

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

continued on the next page

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 remind parents that they will be called again in 7 days (please use the actual scheduled date for follow-up when discussing with the parent/carer) Please confirm the best telephone number to use for the day 14 follow-up call and if possible please try and agree a suitable time for the call.

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)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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