

Standard Operating Procedure (SOP) for: Explaining the completion of the diary card to parents

Baseline visit

- 1) Research Nurse fully completes the front of the diary card, entering the following details: Child's name, Relationship to the child of person completing diary, enrolment number, randomisation number, Doctor/Nurse's diagnosis, and symptoms of illness. The nurse also documents the times that the next doses of paracetamol and ibuprofen are due, and explains this to the parents. It is then reinforced that the times of the 3rd and 4th doses are dependant on the times of the 2nd dose and are 4-6 hours after (for paracetamol) and 6 to 8 hours after (for ibuprofen).
- 2) The nurse completes the date and planned time sections of the card up to and including the 24-hour visit. The time zero is the time at which the 1st dose of medicine is given. The nurse explains to the parent that these are the times we would like them to measure their child's temperature using the study thermometer and they are shown how to use it. It is explained that the box which says "actual time" gives the parent the opportunity to tell us what time they managed to take the temperature and record the 4 scores. Parents are asked to use their watch to complete the time or a reliable clock and are asked to use the same timepiece at each measure rather than guessing the time.
- 3) The nurse explains that as well as taking the child's temperature at these times, we would like them to record 4 scores in respect of the child's discomfort, activity, appetite and sleeping. Each score is talked through with the parent in order to complete the scores for time zero and it is explained that we want them to do the same at each of the times written in the diary card.

It is explained that there is a key at the bottom of the diary card, which explains each score. Parents are asked to choose a score that they think is most suitable for their child. If there is any doubt about which score a child should be given, (for example showing characteristics for 2 scores) then the higher score should be given, rather than the lower score. It is explained that the appetite score 'a' can be used when they haven't been due to have any food or drink.

4) It is explained that the discomfort and activity scores are to be taken **at the time** that the temperature is taken. The appetite and sleeping scores are based on how the child has been **since they were last assessed/scored**. In order to obtain an accurate discomfort score at the baseline visit, the nurse can gauge the child's discomfort from observations in the time that she has been in the home. If the child is sleeping, a discomfort score can be obtained after waking the child up to weigh them. If it is felt that by waking the child and weighing them, this has caused the child to be more distressed (and therefore an accurate discomfort score cannot be obtained) the nurse should discuss with the

parent how the child has been in the last hour or so prior to nurse visit in order to obtain a suitable score. Nurses to document in instances where the discomfort score was obtained by reporting from parents, rather than nurse/parent observation.

- 5) The research nurse records the date & time that the initial study medicines are given with an 'I' or a 'P' beside the relevant time and asks the parent to do the same every time a dose of medicine is given. At this point it is also explained that the box underneath asks how well the medicines were swallowed and the key at the bottom of the page identifies the answers. Again, the research nurse completes the boxes to demonstrate how it is done.
- 6) It is then explained that there is a box for the parent to write down anything else they did to reduce the child's temperature e.g. stripping off, opening windows etc. Parents are asked to record the date and time against any action recorded
- 7) The back of the diary card is then explained. It gives the parent the opportunity to record any new health related problems, and whether the data logger came off. The research nurse reinforces the importance of recording accurate times for when the data logger came off and was replaced. . It is also explained that there is a space for recording telephone or face-to-face contact with any health professionals that the parent has regarding the child with over the study period.

24 hour visit

- 1) The research nurse discusses the diary card with parent to see if it has been fully completed. Any blanks are either completed or an explanation written about why it wasn't completed.
- 2) The times are put in for the checks needed at 32 hours and 40 hours and it is explained that the 48-hour scores will be completed when the nurse next visits.
- 3) The 24-hour temperature and scores are completed, if the parent hasn't already done so, with the parent encouraged to take the temperature and asked for the scores.
- 4) The parent is reminded to complete the sections on medicines and how well they were swallowed, as well as the description of anything else that was done to reduce the child's temperature.
- 5) If the child has been given any NON study paracetamol or ibuprofen, the nurse should clearly document time, dose, type of medicine, and make it explicitly clear on the diary card that these medicines are NOT study medicines. Also note at the top of the card that non-study paracetamol/ibuprofen were given as a prompt for trial secretary when inputting data.

48 hour visit

- 1) Again, the nurse completes the section with the parent regarding the temperature and the scores. The parent is asked whether they have

recorded any study medicines given and how easily they were swallowed.

- 2) The card is checked to ensure it has been fully completed and taken away for the 5-day telephone call.
- 3) If the child has been given any NON study paracetamol or ibuprofen, the nurse should clearly document time, dose, type of medicine, and make it explicitly clear on the diary card that these medicines are NOT study medicines. Also note at the top of the card that non-study paracetamol/ibuprofen were given as a prompt for trial secretary when inputting data.