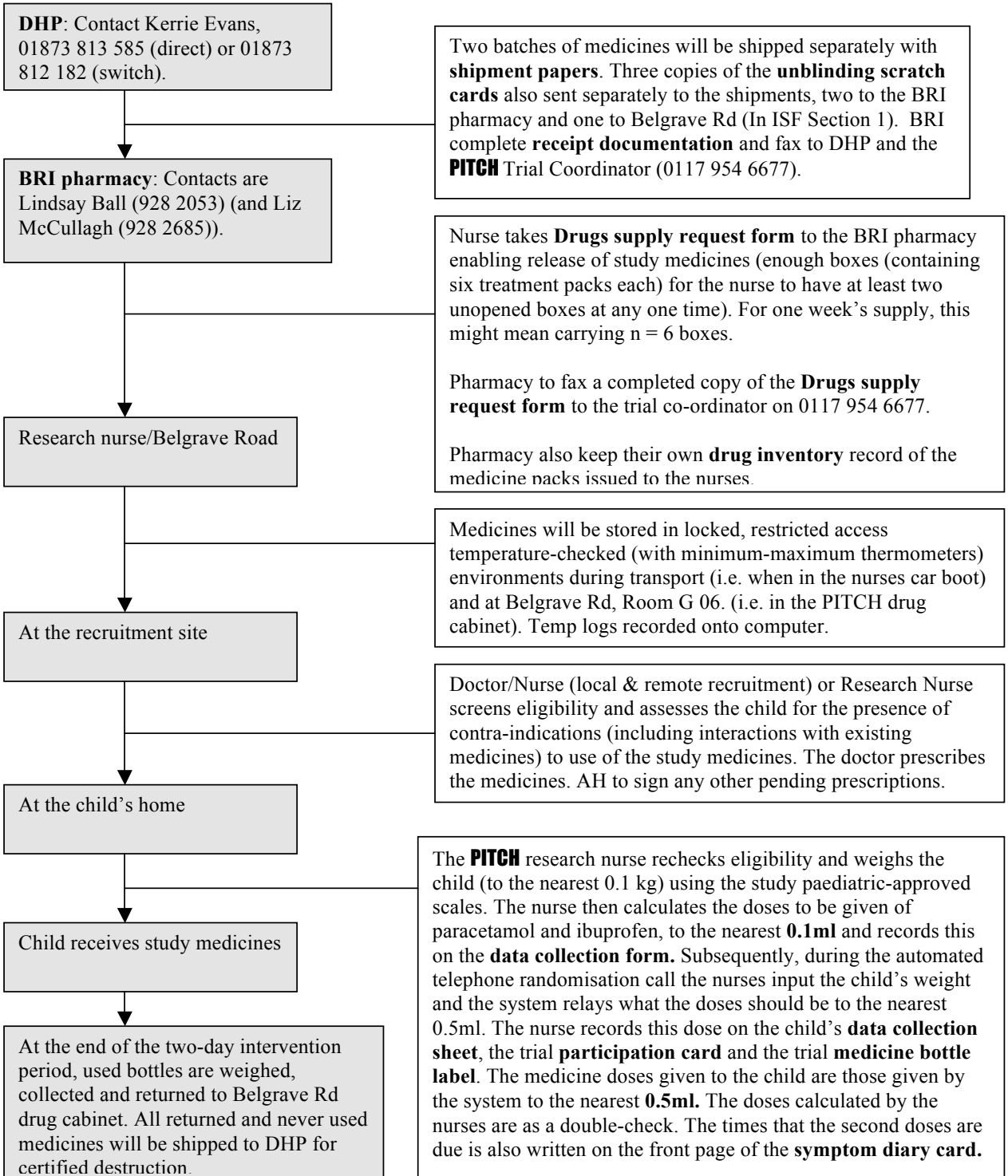


The PITCH trial – Handling, dispensing and administration of the study medicines

Medicine movement

Associated paperwork



Further Notes

Paediatric scales:

- The study paediatric scales read to 2 decimal places (i.e. 0.01kg). However the nurses round down to 1 decimal place (0.1kg). If it reads to 0.04 kg the weight is rounded down, if it reads to 0.05kg or above, the weight is rounded up.

Calculation of doses by nurses:

- Paracetamol dose = **15mg/kg**
- Study medicine bottle contains **120mg/5ml**

Therefore paracetamol dose calculation = $(15\text{mg} \times \text{child's weight}) / (5\text{ml}/120\text{mg})$

- Ibuprofen dose = **10mg/kg**
- Study medicine bottle contains **100mg/5ml**

Therefore ibuprofen dose calculation = $(10\text{mg} \times \text{child's weight}) / (5\text{ml}/100\text{mg})$

The doses calculated are rounded down to the nearest 0.1ml

Administration of first dose of medicines:

- Medicine bottle is shaken
- First dose of study medicines is administered using 5 ml and 10ml oral syringes (whose precision is to 0.5ml). This dose is administered by the parent, in the nurse presence at the baseline visit, with nurse assistance if necessary.

Explanation of subsequent administration of medicines to parents (proactive in first 24 hours and reactive between 24 & 48 hours):

- The time the second dose is due for both medicines is written on the front page of the patient symptom diary card and is highlighted to the parent
- The research nurse explains to the parent that the study medicines need to be given regularly for the first 24 hours i.e. every 4 to 6 hours for the paracetamol (up to a maximum of 4 doses in 24 hours) and every 6 to 8 hours for the ibuprofen (up to a maximum of 3 doses in 24 hours), regardless of whether child is hot or symptomatic.
- The research nurse explains that for the second 24 hours the parent needs to give the doses as they think the child needs the medicine but again not exceeding the maximum dose in the 24 hour period.
- For parents who do not understand the above explanation, the nurse writes down the time of the first dose of paracetamol and Ibuprofen and explains that the child will need 4 doses of paracetamol at least 4 hours apart before the next nurse visit. Similarly that the ibuprofen needs to be given 3 times before the next nurse visit. At the next visit (at 24 hours) the nurse explains that the study medicines need to be given when the child is feeling ill or showing some of the unwell symptoms.
- Parents are advised to keep study medicines out of reach and sight of children

Calculation of doses by the telephone randomization system:

The system uses an algorithm to generate the doses:

- For paracetamol this = child's weight x 0.625
- For ibuprofen this = child's weight x 0.5

The doses calculated are rounded down to the nearest 0.5ml