Paediatric Acute Respiratory Intervention Studies (PARIS II)

Frequently asked questions

1	**If a patient is recruited to the PARIS 2 study and are diagnosed with another disease process instead of an AHRF diagnosis post enrolment, should we remove the patient from the trial?**	**NO**

No - please continue to treat the patient as per the study protocol, as there was an '**Intention to Treat'** for this patient as AHRF from the initial clinicians viewpoint. These patients will be reported on separately in the outcome paper that is written on completion of the trial.

Often the primary diagnosis on discharge may differ from the initial admission diagnosis based on results and observations made during admission. Bronchiolitis and Reactive Airways Disease (RAD) often are difficult to separate in this age group and therefore it may happen that a patient with a true bronchiolitis may get enrolled under the admission of RAD and this may change during their hospital stay however, the study team will keep these children in the trial and report on them.

2	**How do I give a Nebuliser/MDI to a patient on High Flow therapy with the AIRVO2 device?**

During administration of the nebuliser/MDI reduce the flow down to 2L/min (Junior mode) or 10L/min (Adult mode). Do this by decreasing flow using the AIRVO2 up and down arrows. Then increase to 95% FIO2 by slowly increasing the wall Oxygen flow meter and observing the AIRVO2 display screen for the FiO2 value.

After the nebuliser/MDI is finished, return patient to previous AIRVO2 settings, changing both the L/min flow and decreasing the flow meter on the wall to meet the required FiO2 on the machine display screen.

If you are not able to achieve a good seal with high flow therapy nasal cannula in place when administering medication with a MDI, then you will have to remove the nasal cannula and administer the medication via the MDI and then return the patient to high flow therapy and previous settings used.

3	**A patient being recruited to the trial also has Tracheomalacia – are they still eligible to be recruited?**	**YES**

In the Exclusion Criteria "Upper Airway Obstruction" refers to children with Croup and Anatomical upper airway malformations. An example of this exclusion criteria is Laryngomalacia. However, patients with Tracheomalacia and Bronchomalacia can be recruited to the Trial.

4	What size nasal cannula should I use for High Flow therapy patients?

Patients > 12.5kg, who will use the adult circuit, use either the **small (Orange colour); medium (Blue colour)** adult cannula. These adult cannula are provided for patients >13kgs to meet required weight specific flow rates (please refer to your lanyard cards for flow rates). The appropriate cannula should be selected dependant on patient comfort and face size. Please maintain a leak at the nares when applying the nasal cannula to ensure air can be entrained around the cannula. The cannula should not occlude the nares.

Patients < 13kgs, who will use the junior circuit, you will use the Junior **Green Optiflow cannula** to achieve the lower flow rates required for these infants.

5	Do I use a battery to transport a patient on High Flow therapy to the wards from ED?	YES

Yes – if the external battery is available please use this. However, **if the external battery *is not available*** (and the patient is not high flow dependant) please use the transport oxygen tubing that interlocks with the green and purple Junior Optiflow cannula to deliver standard low flow oxygen without disturbing the patient by removing/replacing the cannula. Please recommence previous high flow settings once patient has been transported. A patient with mild to moderate AHRF is unlikely to decompensate during the period of the transfer. For the children on the orange or blue adult nasal cannula you will have to use a Hudson mask for transfer if a battery is not available in your centre.

6	How many times can the same patient be enrolled in the study?

A patient can have one enrolment/randomisation per admission – if they are on the trial and weaned off CONTROL or HIGH FLOW and drop their Sp02 <90/92% (dependent on hospital SpO2 threshold), they need to be recommenced on the same therapy, be that CONTROL or HIGH FLOW, and the weaning process begins again.

If the patient represents to the hospital again (and again) then they can be placed on the trial if they meet the inclusion criteria. New admissions require a new randomisation, a new patient booklet and a new consent form to be completed.

7	Is the patient Obstructive or Non-Obstructive?

A child with **WHEEZE is Obstructive** and defined by ongoing oxygen requirement at time of randomisation. This may include the known Asthma child that has an absent wheeze post therapy given.

A child with an **ABSENT WHEEZE is Non-Obstructive** and defined by ongoing oxygen requirement at time of randomisation.

8	If the patient is weaned off FiO2 and High Flow therapy then ceased, and the patient then desaturates (only when asleep) with SpO2 ≥90/92% (dependent on hospital SpO2 threshold) when awake; do we put the patient on High Flow therapy again?

If the patient desaturates <90/92% (dependent on hospital SpO2 threshold), then the patient needs to go back on High Flow therapy immediately whether awake or asleep. The patient may only require their set flow in room air (FiO2 @ 21%). Aim for SpO2 between 90/92-98% (dependent on hospital SpO2 threshold). If their SpO2 remains in

this range for 4hrs on room air, then turn High Flow therapy off again and observe the patient.

9	**When can I wean the patients FiO2 (High Flow patient) or standard wall Oxygen (Control patient)?**

When the patients SpO2 is stable between 90/92-98% (dependent on hospital SpO2 threshold), you can then wean the patient's oxygen. You do not need to wait until the SpO2 are at 98% - you can start to wean when the SpO2 are stable ≥90/92%(dependent on hospital SpO2 threshold).

10	**Can I give my patient oral feeds on High Flow therapy?**	**NO**

Patients should not be orally fed whilst on High Flow therapy due to the potential risk of aspiration.

If a High Flow therapy patient wants to orally feed including eating, drinking bottle/breast feeding, the flow of the High Flow therapy should be turned down to low flow using the AIRVO2 for the duration of the oral intake to the following settings:

JUNIOR MODE: 2L/min flow at 95% Fi02

ADULT MODE: 10L/min flow at 95% Fi02

After a maximum of 20 minutes, oral feeding should be stopped and High Flow therapy recommenced at the previous settings.

11	**The patient has increased work of breathing however the SpO2 remains ≥90/92% (dependent on hospital SpO2 threshold) - Can I recruit to the study for the work of breathing?**	**NO**

No, patients should not be recruited for work of breathing. Only patients that meet ***all four inclusion criteria*** should be recruited. This includes an **ongoing oxygen requirement <90/92%** (dependent on hospital SpO2 threshold), in room air.

It is recognised that this is difficult for the medical and nursing staff to observe and not apply High Flow/Oxygen therapy however this is the reason for the study taking place – **to prove or disprove** the effect and usefulness of High Flow therapy versus standard Oxygen therapy.

Please observe these patients, as they will declare themselves by dropping their SpO2 at some point if this is going to occur.

12	**Should I place an NGT on all High Flow therapy patients?**

NGT placement is at the clinician's discretion. It is encouraged for patients <2-3 years of age for stomach venting and/or feeding, however is not mandated for the study. Please remember High Flow therapy patient's can be fed orally without a NGT by reducing flows on the AIRVO2 for the duration of the feed (**see dot point 10**).

13	**Should I wean the patients flow rate (High Flow therapy patient)?**	**NO**

No, Fi02 is the only value that should be weaned (as per weaning protocol). The patients weight specific flow rate

should remain constant for the entire length of High Flow therapy. The only time the flow should be reduced is for oral feeds for a maximum for 20 minutes, before reverting back to previous High Flow therapy settings.

14	**What is the timeframe for previous Home Oxygen Therapy patients to be off their Home Oxygen therapy to be suitable for study enrolment?**

There is no time frame, so long as it is known that Home Oxygen Therapy has been ceased fully by their respiratory team (even hours prior to hospital presentation) these patients can be included.

15	**When should I obtain consent?**

Prospective consent – for those hospitals using this method, consent needs to be obtained prior to randomisation.

Delayed consent – for all other centres delayed consent should be obtained once the patient is in the paediatric ward or SSU, by the treating medical officer or nurse. Please ensure the consenting parent/guardian signs the consent form in the patient booklet.

Please note that consent is for the research standard oxygen therapy or High Flow therapy.

16	**Which AIRVO mode should I use if I'm applying High Flow therapy to a 12.5kg baby?**

As this baby's weight is 'borderline' for the flow rates (as per weight specific flow rate table) we suggest that they are commenced on **30L/min** on the **'Adult Mode'** to match this child's inspiratory flow.

17	**What if my patient does not 'tolerate' High Flow therapy?**

The research team recognises that high flow tolerance can be difficult particularly in the 1-5 year old age group. This data will still be collected and reported on in the study. Please try to aid high flow tolerance by choosing the appropriate size nasal cannula for age/size and try commencing the patient on a lower flow rate and gradually increase the flow over two minutes. The study AIRVO2 devices have been set to increase in increments of 1L/min up until 35 L/min. Thereafter it increases in 5L/min increments to 60L/min. Try using distraction techniques with the child and observe how the rates are tolerated.

If you decide that your patient will not tolerate High Flow despite attempts, then treat the child with whichever oxygen therapy is agreed upon by the treating team that the child will tolerate. Please document this in the study booklet and gain written parental consent for the data.

18	**How do I document High Flow/Control settings on the early warning tool chart?** **QLD centres will use the PARIS 2 Trial CEWT form. Other centres will use their standard observation form and document in a similar manner.**

When on **CONTROL** therapy please document a value in **L/min** (as found on the 0-15L wall flow metre).

When on **HIGH FLOW** please always document the **L/min** flow rate (prescribed as per weight specific flow rate table) as well as the Fi02 value (as displayed on the AIRVO screen). For a patient on High Flow you do not need to document what is going through the wall flow metre.

Room Air = 21% Fi02