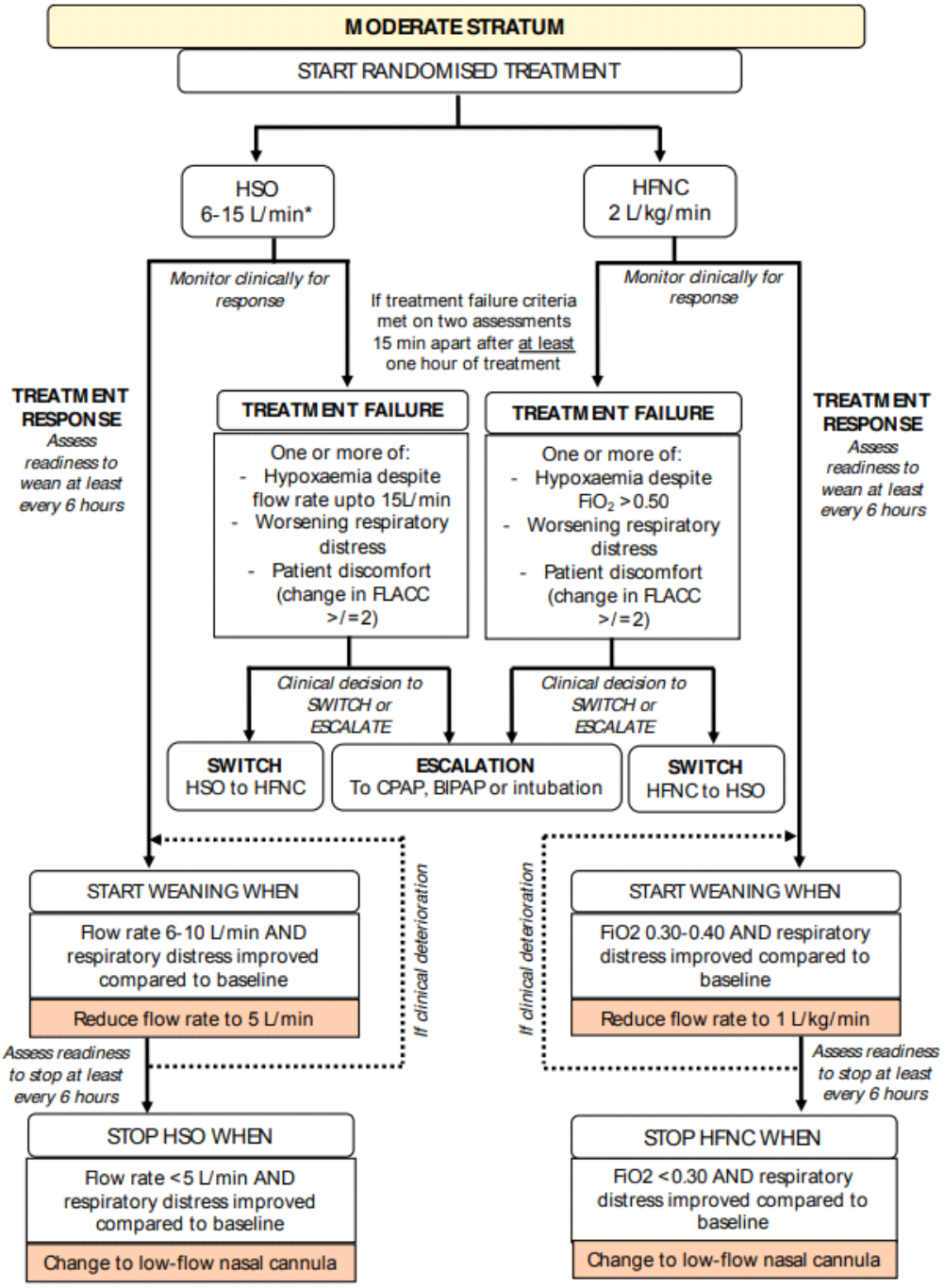
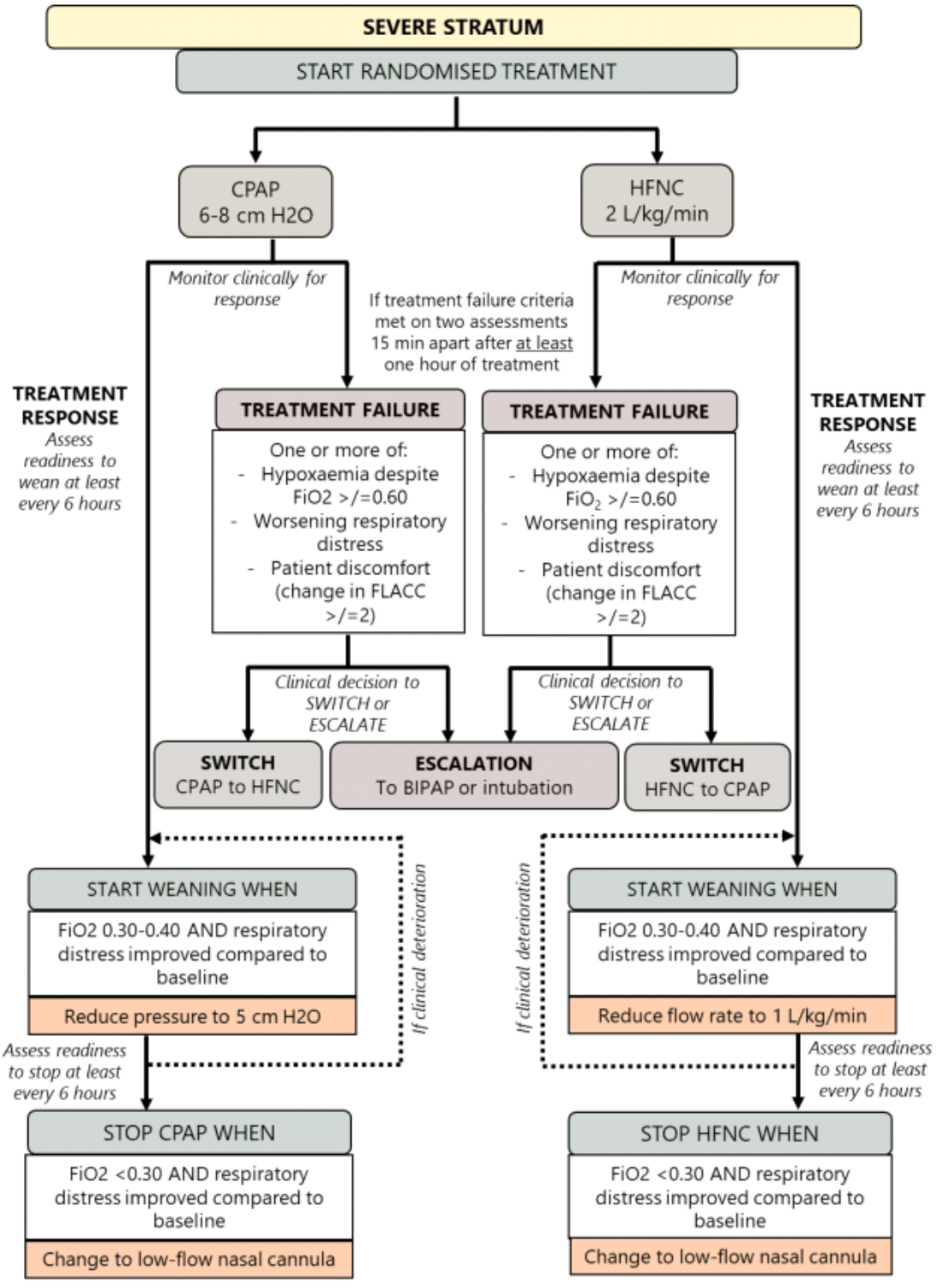
John Radcliffe Hospital

Bach-B treatment guidance notes

TREATMENT



*Titrate flow rate to maintain SpO2 ≥ 90% (or ≥ 92% for babies < 6 weeks, or any age with underlying health conditions)



*Titrate flow rate to maintain SpO2 ≥90% (or ≥92% for babies <6 weeks, or any age with underlying health conditions)

Rescue treatments

In line with current clinical practice (and previous RCTs in this area), and to safeguard patient safety, the treating clinical team will be allowed to use rescue treatments if pre-specified 'treatment failure' criteria are met on two assessments 15 min apart after at least 1 hour of treatment.

MODERATE STRATUM: One or more of the following:

- Hypoxaemia despite gas flow rate 15 L/min (HSO) or FiO2 ≥0.50 (HFNC)
- Worsening in respiratory distress status
- If the allocated mode of respiratory support is not tolerated by the patient (as indicated by a rise in the FLACC score by ≥2).

How to use FLACC

Each category (Face, Legs etc) is scored on a 0-2 scale, which results in a total pain score between 0 and 10. The person assessing the child should observe them briefly and then score each category according to the description supplied.

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaints	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or "talking to". Distractable	Difficult to console or comfort

SEVERE STRATUM: One of more of the following:

- Hypoxaemia despite FiO2 ≥0.60
- Worsening in respiratory distress status
- If the allocated mode of respiratory support is not tolerated by the patient (as indicated by a rise in the FLACC score by ≥2).

Rescue treatments may include a switch of the patient to the alternate mode of respiratory support (e.g., from HSO to HFNC in the moderate stratum, or from HFNC to CPAP in the severe stratum) or one or more escalation(s) (e.g., from HSO to intubation, or from HFNC to CPAP and then to intubation). Rescue treatments will be monitored and recorded and will form part of the protocol.

Trial algorithms

To standardise clinical management of respiratory support treatments in the groups and across research sites, the trial will use evidence-based flow diagrams related to the use of HSO, HFNC and CPAP, including when and how to start, switch and/or escalate, and wean the study treatments. If the patient is escalated to bilevel positive pressure ventilation (BIPAP) or intubation and ventilation, clinical management of the patient thereafter will be outside the study protocol. Similarly, if the patient has come off the study treatment for longer than 6 hours and subsequently requires respiratory support treatment, their clinical management will be outside the study protocol.

HSO

Humidified oxygen can be provided in the trial according to usual clinical practice, **as long as a heater/humidifier is used** as part of the circuit. Passive humidification ('cold' humidification) is not allowed as part of the trial. The most common interfaces used to provide humidified oxygen are face mask or headbox, but other interfaces (e.g., nasal prong) are allowed as per site clinical practice.

Treatment	Equipment	Stock locations
HNFC	Airvo	ED, Bellhouse and PICU
CPAP	Hammilton medical	PICU store
HSO	MR850	ED Research Lab

MR850 + circuit: Located in the research lab.

Sterile water + oxygen tubing: Available in the ED store.

Paediatric nasal prongs: Stocked in both the ED paediatric area and the resus store room.

Folder in ED Paediatrics research drawer contains the following

Study protocol

Recruitment guide

Treatment flowchart

Randomisation cards

Participant information sheet (PIS)

Consent form

HFNC

Any approved medical device capable of delivering heated, humidified, high flowthrough nasal cannula can be used to provide HFNC at the prescribed gas flow rate during the trial. Staff in all participating units will already be using HFNC – therefore, no additional technical training related to the use of HFNC will be required for the study.

CPAP

Nasal CPAP will be started using an approved medical device at an expiratory pressure of 7-8 cm H2O. The trial does not specify a specific device or patient interface for the provision of CPAP. Staff in most participating units already use CPAP – therefore, significant additional technical training related to the use of CPAP will not be required for the study.

Co-interventions

All other usual care will be provided at the discretion of the treating clinical team, as per local practice.