FIRST-line support for Assistance in Breathing in Children

Participant Information Sheet (Parents or Guardians)

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We would like to invite you to provide consent for your child's information to be used in a research study

We would like to offer you our heartfelt condolences. We know that this is a very difficult time for you and your family. We hope you won't mind spending a few minutes deciding on whether or not you would consent for your child's information to be included in a research study, which aims to improve the care of children in intensive care.

Before you decide whether you want to give permission for your child's information to be included in this study, it is important for you to understand why this research is being done and what it involves. You are free to decide whether or not you wish your child's information to be included in this study. Please take time to read the following information.

Please ask the nurse or doctor who has spoken or written to you about anything that is not clear, or if you would like more information. Talk to others about the study if you wish.

Your child needed breathing support while they were in the intensive care or high dependency unit. Currently, there are two main methods of providing this type of support non-invasively. The first is called Continuous Positive Airway Pressure (CPAP). This method has been used for a long time and involves providing oxygen/air through the child's nose or through a face mask. The second method is called High Flow Nasal Cannula (HFNC). This method is newer and involves giving oxygen/air through tiny tubes inserted into the child's nostrils. Both methods have a similar effect on the lungs and are used across the NHS, with some hospitals using CPAP more often, and others, HFNC.

Why are we doing this study?

We are doing this study (FIRST-ABC: FIRST-line Assistance in Breathing in Children) to compare HFNC to CPAP when used as the first treatment option for non-invasive breathing support.

Breathing support is the most common treatment provided to children in the intensive care or high dependency unit. Even if the main problem is not with the lungs, breathing support is often a vital part of their treatment. Non-invasive breathing support is mainly used to help prevent a child from needing to be put onto a breathing machine (ventilator) or from going back onto a ventilator after coming off one. The two main ways of providing non-invasive breathing support are CPAP and

HFNC. Currently it is not clear which of these two methods should be used as the first treatment option for unwell children.

CPAP (Continuous Positive Airway Pressure) is a method that has been used for over 30 years. This method is quite effective – 4 out of 5 children get better on this treatment without needing further breathing support. However, some children find it uncomfortable and do not tolerate it.

HFNC (High Flow Nasal Cannula) is a newer method that has started to be used over the last 10 years. Less is known about how effective HFNC is when compared to CPAP, but some children appear more comfortable on HFNC.

Our aim is to find out whether HFNC is as effective as CPAP for children who need non-invasive breathing support in the intensive care or high dependency unit. It is not yet known if one method is better than the other or if one method is more suitable for more children.

This hospital is one of around 25 hospitals around the country that are taking part in FIRST-ABC. This is a large national study involving 1,200 children. We will monitor the study closely and, if it is clear that one treatment is better, or worse, we will stop the study.

Why was my child chosen to be included in this study?

Your child was chosen to take part in the study because the doctors and nurses decided that they needed non-invasive breathing support. We hope to include 1,200 children in the study.

What do I need to know about the treatments used in this study and the possible side effects?

Both methods are already widely used across the NHS to provide non-invasive breathing support. The only difference was that the first treatment option was chosen by the study rather than the doctor.

Your child was monitored closely and their doctor would have switched to the other method or used other forms of breathing support if needed. Any complications will have been managed in the same way as they would have been even if your child was not involved in the study.

What are the risks or side-effects of the treatment that my child will receive?

No significant safety concerns about either treatment have been reported. However, as with all treatments there are risks of complications. With the CPAP (Continuous Airway Positive Pressure) method these include air leaking outside the lungs, vomiting from stomach bloating from the oxygen/air, and pressure sores on the nose or cheeks from the face mask, but these do not happen very often. With the newer HFNC (High Flow Nasal Cannula) method these include pressure sores on the nose or cheeks from the tubing, again these do not occur very often.

If for any reason the doctors felt that your child did not improve as expected, they will have switched to the other method or used other forms of breathing support. All other aspects of care, including medicines, will have followed usual NHS practice and were not related to the study.

How was it decided which method of breathing support my child was started on?

FIRST-ABC is a 'randomised clinical trial' - which means that each child is randomly put into one of two groups:

- Children in Group 1 receive CPAP as the first option for treatment
- Children in Group 2 receive HFNC as the first option for treatment

To make sure it is fair, children are put into the groups at random by a computer programme. This means that your child had an equal chance of being in Group 1 or Group 2.

What treatment would my child have received if the study was not taking place?

The first treatment option that your child would have received if they were not part of the study would still have been CPAP or HFNC, but the decision would have been made by your doctor instead of the study.

Why am I being asked after my child received the treatment, rather than before?

As this was a time-sensitive emergency situation, we could not delay starting the treatment your child needed. Explaining the study to you in advance would have caused a delay in giving your child urgent treatment. We have therefore come to talk to you about the study afterwards. This is called "research without prior consent", a method of consent which is used in similar studies.

Who is funding and organising the study?

The study is funded by the National Institute for Health Research, Health Technology Assessment Programme. Dr Padmanabhan Ramnarayan is the Chief Investigator (the person leading the study). The Great Ormond Street Hospital for Children NHS Foundation Trust are the Sponsor for the study. The Intensive Care National Audit & Research Centre (ICNARC) are managing the study. All are based in the United Kingdom.

The research team are qualified to do this study because they have all the specialties and skills needed, including caring for unwell children and doing health research. Parents of children who have experienced intensive care have been involved in developing of the study, including this information sheet and how you were asked to take part.

Do we have to take part?

No. Participation is **voluntary**. It is up to you to decide whether your child's information will be included in the study.

What will happen next?

1. If you agree to continue in the study, the hospital research team will use the anonymised information about your child's treatments already collected for FIRST-ABC. This information will be securely sent to the Intensive Care National Audit & Research Centre (ICNARC) who are managing the study and will analyse the results at the end of the study.

2. Information collected from research studies can be used to address many important research questions beyond those planned in the original study. This has the potential to provide real

benefit to patients, the NHS and the scientific community. If possible, we would like your permission to share anonymised information about your child with other approved researchers if we feel it could contribute to answering other important health questions. Examples of anonymised data would include your child's age, what treatments they were given or how long they were in hospital. The other researchers would not be able to identify you or your child.

3. We would also like to ask for your permission to contact you about any future related research studies where we feel your views and opinions would be valuable (for example, to take part in an interview discussing a new research study related to intensive care). If you agree to this option, we will keep your contact details for up to five years after the end of the study.

All of the options listed above are voluntary and you can change your mind at any time. If you agree to any of them, we will ask you to sign a Consent Form. To leave the study at any point, you can either contact the Principal Investigator or Research Nurse (the doctor and nurse leading the study at this hospital) using the details on the last page of this leaflet or by contacting the Intensive Care National Audit & Research Centre (ICNARC) by phone on 020 7269 9277 or email to firstabc@icnarc.org.

Will the information be kept confidential?

Yes. We will follow the law (Data Protection Act 2018) by making sure your information is kept private and secure.

How will my child's information be used and what are my choices about how it is used~~will happen to it~~?

Both Great Ormond Street Hospital for Children NHS Foundation Trust and the Intensive Care National Audit & Research Centre (ICNARC) are responsible for looking after your information and using it properly. [NHS Trust] will collect information from you and your child's medical records for this research study in accordance with our instructions (as described earlier) and will pass this onto ICNARC. ~~This information will include relevant health information, which is regarded as a special category information. ICNARC will use the information from your child's medical records in order to manage the study and find out whether HFNC is as effective as CPAP. ICNARC will store all information securely and keep the research data for up to 15 years. [Local NHS Trust] will keep identifiable information about your child from this study for fifteen years after the study has finished. Great Ormond Street Hospital for Children NHS Foundation Trust will not receive [new] identifiable information about you or your child that has emerged from this study.~~

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your or your child's name or contact details. Your data will have a code number instead. Once we have finished the study, we will keep some of the data so we can check the results.~~Individuals from ICNARC and regulatory organisations may look at your child's medical and research records to check the accuracy of the study. The only people from ICNARC who will have access to information that identifies you or your child will be those who will audit the data collection process. The people who analyse the information will not be able to find out yours or your child's name, NHS number or contact details.~~

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you or your child. You can stop being part of the study at any time, without giving a reason, but we will keep information about you and your child that we already have.~~Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard you and your child's rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at:~~
~~www.icnarc.org/Our-Research/Studies/FIRST-ABC~~

Where can you find out more about how your information is used?

You can find out more about how we use your information;

- at www.hra.nhs.uk/information-about-patients/
- at www.icnarc.org/Our-Research/Studies/FIRST-ABC
- by asking one of the research team
- by sending an email to firstabc@icnarc.org

What will happen to the results of this study?

The results of the study will be published in scientific journals. You will be able to find the results on ICNARC's website (www.icnarc.org) within a year after the study is completed. We will write our reports in a way that no-one can work out who took part in the study.~~It will not be possible to identify any person who has taken part in the study in any reports or articles.~~

What if there is a problem?

Complaints: If you have a concern about any aspect of FIRST-ABC, you should ask to speak with the Principal Investigator <Insert NAME> or research team at your hospital who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or the Patient Advisory Liaison Service (PALS), contactable on <Insert PALS number>. You may also have the right to lodge a complaint with the Information Commissioner's Office (ICO) (www.ico.org.uk).

Harm: It is very unlikely that the research would cause any harm, but we are obliged to mention this possibility. If something does go wrong, and the participant was harmed during the study and this is due to the design of the study or someone's negligence then you may have grounds for a legal action for compensation against Great Ormond Street Hospital for Children NHS Foundation Trust, but you may have to pay your legal costs. The normal NHS complaints mechanisms will be available to you.

Who has reviewed the study?

All NHS research is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. FIRST-ABC was reviewed by the East of England - Cambridge South Research Ethics Committee who approved the study and agreed it is being conducted in a correct and appropriate manner.

We are very grateful that you are considering taking part in this study - thank you very much for your time.

If you have any questions, please contact:

Principal Investigator	**Research Nurse**
Name:	Name:
Telephone:	Telephone:

Important things that you need to know

- Your child needed non-invasive breathing support during a time-sensitive situation and it was important that we treated them as quickly as possible.
- Both CPAP and HFNC are widely used all across the NHS, but it is not clear which one should be used as the first treatment choice.
- As this was a time-sensitive situation, your child was started on either HFNC or CPAP as part of the study. They would had been started on one of these treatments even if they were not involved in the study.
- This type of research is called 'research without prior consent' and is done in time-sensitive situations when comparing treatments to find out which is best. We are now asking for your consent for your child's information to be included in the FIRST-ABC Study.

Helpful contacts and sources of support

Child Bereavement UK - open 365 days a year, including weekends and public holidays, the Child Death Helpline is for anyone affected by the death of a child of any age, from pre-birth to adult, under any circumstances, however recent or long ago. It is staffed by experienced and trained bereaved parent volunteers.
Freephone: 0800 800 6019 (free from a mobile) / 0800 282 986 (free from a landline)

The Lullaby Trust – provides expert advice and emotional support for bereaved families and raises awareness.
Freephone: 0808 802 6868; **Email**: support@lullabytrust.org.uk.

At A Loss - committed to ensuring that everyone in the UK who has suffered a significant loss can locate local support. The website aims to provide an access point to a range of bereavement support option and resources.
Website: https://www.ataloss.org/