Brighton and Sussex University Hospitals NHS Trust

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High Flow humidified oxygen as an early intervention in children with Acute Severe Asthma: A feasibility study.

Participant Information Sheet (Parent/Guardian)

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

Although we understand that this is a very difficult time for you and your family, we would like to ask you to spend a few minutes deciding on whether or not you would consent for your child's information to be included in a research study. The aim of this study is to improve the treatment of children with acute severe wheeze.

The HiFlo Study is a feasibility study - one which is being done to help us to design a future larger study (clinical trial) which would be conducted across the UK. This study aims to gather the essential information we need to find out if it is worthwhile and possible to do a large-scale national study. We need to find out if the trial procedures work smoothly and gather the views of parents and staff involved, to see if alterations are needed for the larger scale study.

Before you decide if you want to give your permission for your child's information to be included in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether or not you wish for your child's information to be included. Please ask the nurse or doctor who has spoken to you about this study if there is anything that is not clear or if you would like more information.

Important things that you need to know

- Your child came to hospital with a severe wheezing attack which did not respond to the initial inhaler treatment given in the first hour, and so their treatment needed to be 'stepped up' to a higher level.
- There are a number of choices for stepping up treatment; they are all safe and widely used, and doctors vary as to which option they choose as the next step. One of these options is to start High Flow humidified oxygen (**HiFlo**). Other options include giving a medicine into a vein: this is the most usual treatment at present (**Standard Care**).
- We want to find out which of these options is the **best next step** if children do not respond to initial treatment of severe wheezing.
- As this was a medical emergency, there was no time to delay your child's treatment by asking for your consent. Your child was treated with either Standard Care or HiFlo option as the next step, but could receive either option later if needed.
- This is called 'research with deferred consent'. This kind of research is done in emergency situations when two forms of treatment are being compared.
- We are now asking for your consent for your child's information to be included in the HiFlo Study.

1) Why are we doing this study?

Your child was admitted to hospital with a severe wheezing attack. They may or may not have a diagnosis of asthma. Because your child's wheezing was not getting better with the initial treatment, we needed to "step up" the treatment to a higher level. We are doing this study to improve the treatment of children with severe wheeze by exploring **what is the best choice for stepping up treatment.**

There are a number of choices for the next step: we know that they are safe and effective, but we do not know which is the **best next step**. Different doctors across the UK - even in the same hospital - go for different options as the next step. Currently, the most common practice, if a "step up" is needed, is to give an asthma medication into a vein **(Standard care)**, but another option is to give lots of moist oxygen to breathe by short soft tubes that fit just into the nostrils **(HiFlo)**. HiFlo is effective in other breathing problems, and is being used increasingly in severe wheezing. However, we do not yet know whether HiFlo or Standard Care is the best choice for stepping up therapy. This hospital is one of 3 that are taking part in this study across the country, and the study will involve 70 children in total.

As this is a feasibility study we also want to know about your thoughts and experiences about the study. It is an important part of undertaking research and your opinions are valuable.

2) What do I need to know about the treatments used and possible benefits and risks?

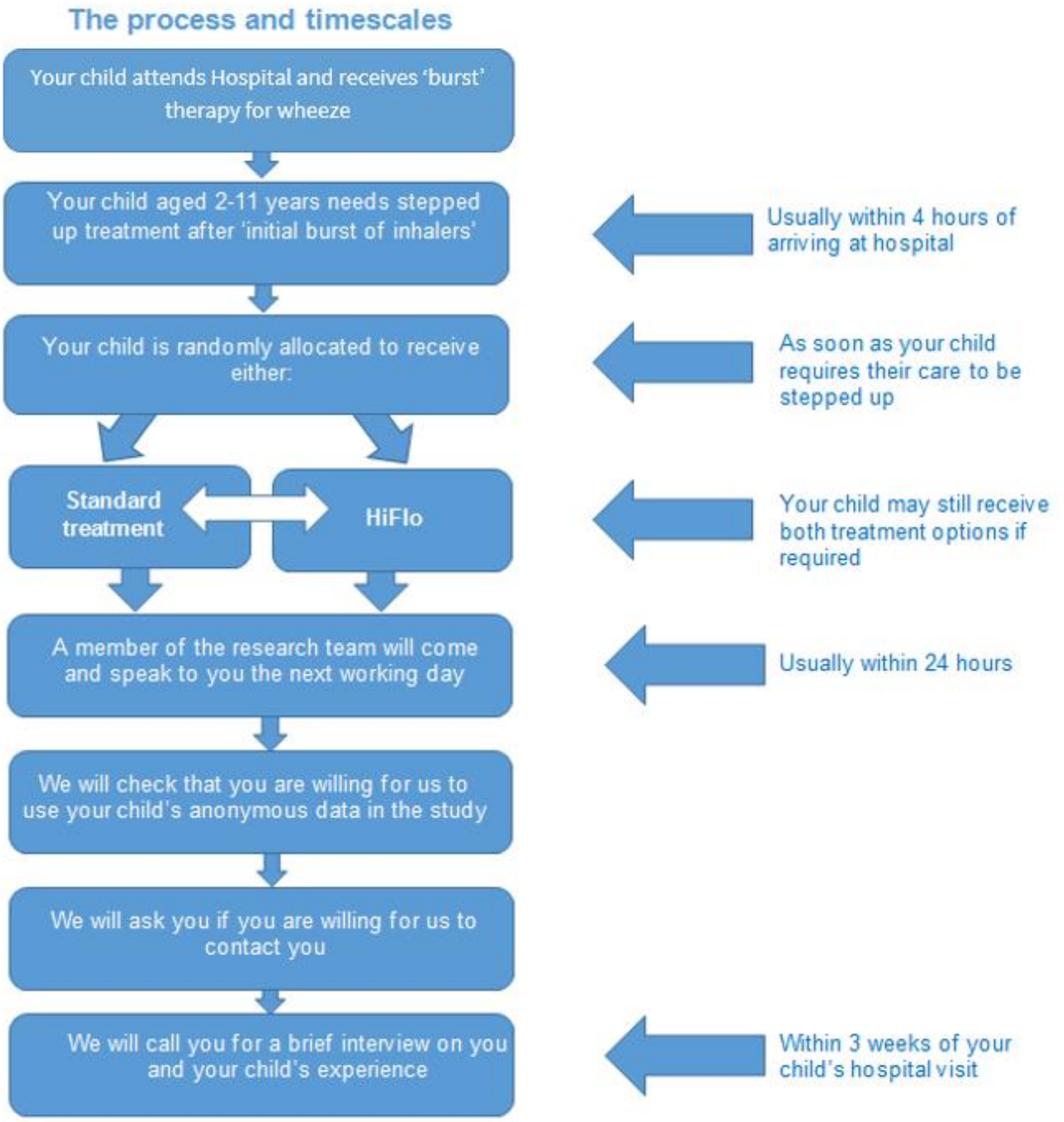
Children with severe wheezing need treatment urgently to help open up their small airways and clear mucus. Drugs given into a vein (IV medications) work mainly by relaxing the muscles of the airways, allowing them to open up. Their side effects may include pain from placing the needle in a vein, fast and sometimes irregular heartbeat, nausea or vomiting, and changes in salt levels in the blood.

HiFlo is thought to work by assisting the work of breathing, helping to hold the airways open, and keeping mucus moist and easy to clear. Side effects of HiFlo may include discomfort to the nose and a small risk of leakage of air from the lungs. Occasionally children find the sensation of the air blowing into their nostrils uncomfortable, especially when faster flowing oxygen is needed. In these instances we may use sedating medicine to make children feel more comfortable

Both treatment options are already widely used in hospitals in the UK (including those taking part in this study), and staff are trained to monitor for these side effects. We cannot promise that your child benefited directly by participating in this study. The benefits and risks of receiving Standard care or HiFlo as the next step, in children who do not respond to initial wheeze therapy, are unclear at this time – which is why this research is needed. Ultimately this study will help to improve the future treatment of children with severe wheezing/asthma.

3) How was it decided which step-up treatment my child received?

The HiFlo Study is a randomised controlled trial, which means that each child is randomly put into one of two groups by a computer programme. One group receives **Standard care** (IV medications) as the next step, while the other group receives **HiFlo**. Your child had an equal chance of receiving Standard care or HiFlo as the next step. However, your child could subsequently receive the other treatment option if the treating team feels it is in their best interest. In other words, your child is not being denied any treatment they may need as a result of being in the study.



4) Why am I being asked *after* my child has been given the treatment rather than before?

As this was a medical emergency, we could not delay stepping up the treatment your child needed for the severe wheezing. Explaining the study to you in advance takes time that would have caused a delay in giving your child urgent treatment. Families have also told us that they find it very difficult to take in information about a research study in an emergency situation when their child is very ill. We are now asking for your permission to use information about your child's hospital stay for our research. This is called 'research with deferred consent' – a method of consent which has been used in other emergency studies.

5) What do I need to do now?

All that you need to do now is take time to think about the information we have given you and decide if you are happy for us to use the information we are gathering routinely during your child's care.

If you agree for your child's information to be included in the study, the hospital research team will anonymise this information. This means that it cannot be traced back to you or your child, it will be stored securely as part of the study. We will later use this information to compare the progress of children who received the two different step-up options.

When your child is ready to go home we will ask you to complete a very short questionnaire about your experience. We may wish to contact you by telephone, within 3 weeks of your child going home, to ask some further questions about your family's experience and views.

If you do not agree for your child's information to be included in the study, the research team will not collect or analyse the data, and we will not ask you to complete a questionnaire, or telephone you after the hospital episode.

Whichever choice you make, your child will continue to receive the best care possible.

If you would like to find out the results of the study, please indicate this on the consent form and we will send you a summary of what we have found by email or post.

6) Who is involved in this study, and what happens to my child's data?

The study is being run by experts in Respiratory medicine and Emergency paediatrics in 3 hospitals in the south of England, in Brighton, Southampton and London. The National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) programme is funding the study. Professor Paul Seddon, a Paediatric Respiratory Consultant at Brighton & Sussex University Hospitals NHS Trust (BSUH NHS Trust) is the HiFlo Study Chief Investigator, and the local Principal Investigator in this hospital is Dr Akshat Kapur. Children who have been in hospital with severe wheezing and their parents have been involved in the development of this study, including this information sheet and how you were asked to take part.

The study has been reviewed by the NIHR RfPB, the Health Research Authority and the West Midlands - Solihull Research Ethics Committee (REC reference: 19/WM/0219). The study is sponsored by BSUH NHS Trust and managed by the Brighton & Sussex Clinical Trials Unit. The sponsor is responsible for looking after your information. To safeguard your rights, we will use the minimum personally-identifiable information possible. If you withdraw from the study, we will keep the information about you that we have already obtained. BSUH NHS Trust will keep your information for 5 years after the study has finished.

You can find out more about how we use your information [at https://www.hra.nhs.uk/information-about-patients/ and/or by contacting the BSUH Data Protection Officer on Tel: 01273 696955.

7) What if there is a problem?

If you have a concern about any aspect of the HiFlo Study, please ask to speak with the hospital research team (contact details are at the end of this sheet) 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 your child's hospital Patient Advice and Liaison Service (PALS).

Brighton & Sussex University Hospitals NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study. If your child is harmed due to someone's negligence or as a result of taking part in the study, then you may have grounds for legal action and compensation. If you wish to complain, or have any concerns about any aspect of the way you or your child have been treated during the course of this study, then you should immediately inform the Principal Investigator. The normal NHS complaints mechanisms are also available to you. Please visit http://www.nhs.uk/ to find your local Patient Advice and Liaison Services (PALS) services contact details. Support and advice for parents whose child has experienced severe wheezing can be obtained from the charity Asthma UK: https://www.asthma.org.uk/

Thank you for reading this.

Contact details:

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