



The children's heart study

Paediatric Cardiac Surgery Impact study

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This study aims to select, define and measure the complications that may follow cardiac surgery and that have the most impact on patients and families.

Welcome to our first newsletter

Inside this issue:

How we chose the complications	2
Table of complications after surgery	2
A day in the life of a busy research nurse	3
A message from the BDA researchers	3
Contact details for five study centres	4
Word search	4
The How and Why of this Study	4

Special points of interest:

- * BDA Study—1200 children took part
- * Incidence and Impact Study under way
- * Nationwide Study with five Centres across the UK
- * Find links to further information on the back page

In the next issue:
updates from our Study
Centres around the UK

Phase 1: Brief Developmental Assessment, 'BDA' 1200 participants—THANK YOU!

The BDA study came to a close in August this year. The study started in 2014. Children had a developmental assessment with one of our researchers. The assessment involved the new BDA as well as already tried and tested developmental assessments. Parents received a written report a month or so after and the children received a young scientist certificate! We have been overwhelmed by the amazing response of families: **1200 took part!** We would like to say a huge **THANK YOU** to



all the families and children. Families often gave up time before or after attending a busy clinic appointment; some were inpatients on the ward and some made a special trip in to the hospital. Having this huge number of assessments means the results are strong and are now being analysed to validate the Brief Developmental Assessment. The assessment

was developed by a group led by Dr Aparna Hoskote and Dr Jo Wray. The initial results are looking good and we are working towards refining it further. When it is fully validated we hope it will be a valuable tool for assessing babies and children who undergo cardiac surgery. It is hoped it can be used at several points as they grow up to ensure that not only do we look at how their heart is doing but we are better able to keep a careful eye on the whole child too.

Phase 2: Incidence and Impact Study

The children's heart study is taking place in five UK hospitals: **Great Ormond Street Hospital, Bristol Royal Hospital for Children, Evelina London Children's Hospital, Birmingham Children's Hospital, and The Royal Hospital for Children, Glasgow.** The study is looking to see how often any of nine types of complication happen after heart surgery in children (this is called *incidence*) and how much

these complications effect the child and family (the *impact*). We are looking at how often these complications happen in all children who have surgery at each of the five hospitals over 18 months. In about a quarter of these children (half with a complication and half without), we are asking parents if we can stay in touch for 6 months after the initial operation to record the impact.

At the end of the study, we will have a much better idea

of what the most common complications are and what they mean for the child and family. This will mean that we can then plan and test ways to reduce both the occurrence and the impact of these complications. It also means doctors can provide families with much better information about what the future might hold before their child has an operation.

How did we choose the 9 complications?

We spent the first year and a half of the study deciding what complications to study. We listened to families through focus groups and an online forum with the help of the **Children's Heart Federation** and we also combed the academic literature to see what was already known about complications after children's heart surgery. We used this information to come up with a long list of every type of possible complication associated with having heart surgery, from very specific medical problems to broader issues such as post-traumatic stress for parents.

However, it would never be possible to measure everything and it was only feasible to look at up to 10 distinct complications. We asked a special group of 15 people to narrow down the list, taking into account how common complications might be and how much impact they might have on the child or family. This group included surgeons, nurses, cardiologists, intensive care specialists, a psychologist and three family representatives. It took many months and lots of intense discussion to narrow down the list but this rigorous process ended with these

9 complications being chosen for this study: A tenth factor was identified which sits separately to the complications listed below but was included after listening to families in the focus groups and online forum—this was *poor communication between the clinical team and family*. We recognised that if a family felt unprepared to care for their child at home it may lead to a worse outcome for that child. It was felt to be important to understand the impact this may have on the child undergoing cardiac surgery and the family.

Families taking part in the impact study are recruited by one of our research nurses while their child is an inpatient. They will then be asked to fill out some questionnaires on the day of discharge and at 6 weeks, 3 months and 6 months after surgery.

Complications after surgery	Description / comments
A new problem with the brain or nervous system.	This was consistently highlighted by parents and clinicians as the most important potential complication after surgery.
Unplanned re-operation	This measures whether the child needed to have another unexpected operation shortly after their main operation. Parents raised this as a scary & worrying experience.
Mechanical support for the heart (ECLS/ECMO)	This is a rare but serious complication when the child's heart needs to be supported by a mechanical pump after the operation
Necrotising enterocolitis (NEC)	Sometimes when the heart is not pumping blood very efficiently, parts of the child's bowel can be damaged due to poor blood flow, which causes this condition.
Prolonged problems with fluid around the lungs / chylothorax	Sometimes after surgery a build-up of fluid can occur around the lung or lungs, needing to be drained by a small tube.
Problems feeding	Many factors can lead to longer term problems with feeding, and because families said feeding was often difficult after surgery, we felt it was very important to measure this.
Major adverse event	This describes a collection of adverse events that can happen while the child recovers from surgery. For instance, if the child has a cardiac arrest in intensive care that would be considered as a major adverse event.
Kidney problems	Sometimes a (usually temporary) reduction in blood flow can cause the kidneys to work less well than normal, leading to a support called dialysis being required.
Hospital acquired infection	This includes wound infections after surgery and also infections that can happen in the tubes connected to children in intensive care.

A day in the life of a research nurse

After a bustling journey into work on the tube, I pick up my morning coffee from a local café to help me focus on the day ahead.

By 8am I'm at my desk in the offices behind the Cardiac Intensive Care unit. A quick gulp of coffee and I'm off to a meeting with the ICU team to hear about all the children on the unit and what is planned for the day.

Then it's back to my desk to update my database with current information about the patients who have had cardiac operations. As soon as I can I'm away again meeting families on the ICU and cardiac ward, handing out the parent and patient information sheet, answering questions about the study and taking consent from children and their families. To take part in the study every family needs to know about the study and what it means to take part. We have information leaflets to explain all about it.

Once a family is happy to take part they give their consent which involves signing a form. Today I consented a family to the study whose baby is recovering from an operation on the Cardiac Intensive Care Unit. The baby has suffered some complications and has been in hospital longer than anticipated after the surgery but is now making a good recovery. I will meet the family again on the cardiac ward before they go home to make sure they have a Study Patient Pack and to help them get started in the study by completing the discharge questionnaire.

After that I'm back to my desk again to make phone calls to parents to help with completing the questionnaires at 6 weeks, 3 months and 6 months after their surgery.

An average day will have me running to meetings too. Some are about the study



itself and will be with all the people involved in the study; there's me and doctors, surgeons, mathematicians, psychologists and researchers. I also attend planning meetings of children that are having surgery in the next week so that I keep as up to date as possible and know all about the children coming

into the unit. This helps to keep me in touch with members of the cardiac team too, such as the nurses and doctors on the Intensive Care Unit and the ward, as well as the cardiac nurse specialists and nurse practitioners.

At 6pm my day at work is coming to a close. By 6:30pm I'm back on that jostling tube on my way home and tomorrow is another day on the Incidence and Impact Study.

A message from the BDA Research Assistants



After nearly two years and 1211 assessments our roles with the Brief Developmental Assessment research study are complete. We have assessed children with a wide

range of cardiac diagnoses from whom we gained so much more than their data and developmental scores. We have been privileged to meet so many incredible children and their families.

Support for Research. One of our main findings and something we discovered very early on in our roles, was how obliging and willing our families were to support research. Families were coming into one of the three hospital sites for potentially anxiety provoking appointments or procedures; however they would be more than happy to spend an hour extra in the hospital to complete this research with us, all to support future children and

their families. Parents, carers and children have given us countless rich understandings of their experiences and their difficulties, as well as their achievements and successes. The altruistic nature of our families was truly an essential part of the success of the BDA Study.

Resilience of families. As well as their altruism, we found the resilience of the families that access our services remarkable. It's hard to imagine how difficult it must be to have a child who may be very poorly, and having not experienced it ourselves, it was initially hard to ask the difficult questions necessary to gain this rich understanding. However it was the families themselves that put us at our ease. We quickly learnt just how resilient these families were, despite experiencing some of parent's worst fears. We found the parent's and children's resilience incredibly grounding and humbling, both professionally and personally.

Overall, our time as part of the BDA phase of this major project, has been as remarkable as one would expect working in some of the leading Children's Hospitals. We would like to say a massive thank you to ALL the children and families who were involved in the BDA, as well as all the support from colleagues. Not only were we, and we continue to be, motivated by our esteemed colleagues but, we were and are motivated on a daily basis by the resilient, generous and wonderful children and families our research and hospitals aim to support.

Rachel, Seona & Anna x



This newsletter comes with thanks to all the families who have and are participating in the Children's Heart Study! Thank you!

If you would like further information about the study or wish to speak to someone about it, then please contact: Prof Victor Tsang or Dr Katherine Brown
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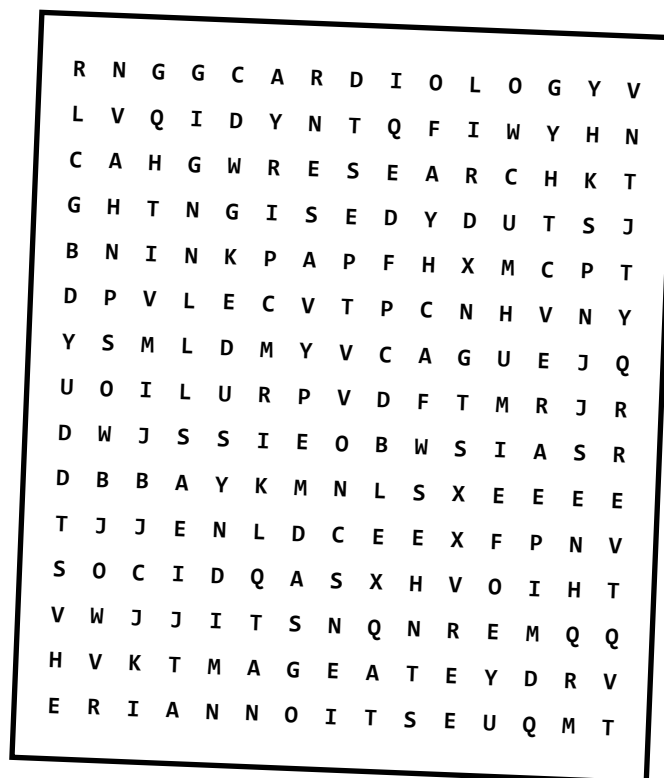
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Anyone wishing to read in more detail about this study follow these links:

<http://www.nets.nihr.ac.uk/projects/hsdr/12500506>

<http://www.gosh.nhs.uk/medical-information/clinical-specialties/cardiotoracic-surgery-information-parents-and-visitors/why-we-do-research/complications-after-heart-surgery-children>

Word Search!



analysis, assessment, cardiology, children, developmental, nurse, patient, questionnaire, report, research, study design

The how and why of this study...

After this study ends (in 2018), the next step is to help all hospitals to monitor these complications all the time and to start trying out ways to reduce how often complications happen. However, we will need to prioritise which complications to target first and we want to make sure to target the complications that have the most impact on children and their families. We also want to make sure that in future we can give parents better information about what it might mean for them and their child if a complication happens after surgery.

We are measuring quality of life for both the child and family, what happens clinically to the child over the 6 months after surgery, how many days the child has to be in hospital in the 6 months after surgery and whether there were financial burdens on the family from caring for the child (for instance if one or both parents had to give up work). We are measuring

these aspects 4 times in 6 months – at discharge from hospital and then 6 weeks, 3 months and 6 months after surgery. As well as measuring these aspects for children who have experienced a complication, we are also going to follow up an equal number of children who had surgery but without a complication – this is so we can separate out the enormous impact of having surgery at all from any additional impact of a complication.



Overall, parents taking part in the study are going to be asked a lot of questions but it will really help us in understanding what happens to children and their families after surgery, especially once they are back home again. **We greatly appreciate all the time and commitment of our participating families.**

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