

Children's Heart Study

Firstly we would like to extend an absolutely MASSIVE thank you to everyone who has helped with the study, including parents, patients, nurses and others. We can't tell you how much we appreciate your help, including especially the time people have spent making this research happen.

Now on to what we found in the study and other news...

Summary of our study

Over 5000 paediatric cardiac surgery procedures are performed in the UK each year and early survival has improved to over 98%. Although early survival is important, most people now think this does not provide enough information. Therefore, we aimed to study health related issues following surgery, generally considered as 'bad for the patient'. The medical term for these issues is "morbidity" but often they are called 'complications'.

We reviewed existing literature, ran three family focus groups and undertook a family online discussion forum. Then a group of health professionals and family representatives considered the possible 'morbidity' and decided on a list of the nine most important ones, which were defined by a group of specialists. This included medical complications such as needing support with a mechanical pump after the operation but also 'morbidity' that were particularly serious to families such as feeding difficulties.

Working in five of the UK centres, we involved children under 17 years old with congenital heart disease (CHD) and their parents to:

- successfully test a new method for nurses to check child development in 1,200 children: we found this worked in children between four months and five years old.
- measure how often 'morbidity' happen in 3,090 children: we found that between a fifth and a quarter experience at least one.
- measure the impact of 'morbidity' in 666 children over six months: one important finding was that although patient quality of life was reduced when these happened, it improved over six months.

We developed new ways to inform parents and the organisation which monitors the results of children's heart surgery (national audit) about complications. Monitoring of 'morbidity' is more difficult than mortality so requires resources and clinician commitment. Further research is needed to work out how best to help children with feeding problems and delays in development.

What are we going to do next?

- We will work with the national audit which is called National Congenital Heart Diseases Audit (NCHDA) hosted at NICOR in Bart's Hospital, to see whether they can analyse some of the complications or morbidity in the future, so that these are monitored in the UK children's cardiac specialist hospitals.
- We will share a method of monitoring the rates of complications or morbidity that we have developed with the children's heart centres, so that individual hospital teams can keep an eye on this better going forwards.
- We will publish papers about the study in journals, so that we can raise the profile of this topic with clinicians and other stakeholders, to help them become better informed about complications of heart surgery that affect the whole child.
- We will test the parent information that we have developed further and work out how this could be used to help with the consent process.
- We are keen to undertake further research into the particular areas that families have raised with us starting with child development and then we hope later with feeding problems. To that end we will be contacting some families that already participated in the study to see whether they are able to participate again.

The Children's Heart Study and your personal data

Introduction

On 25th May 2018 new rules were introduced about personal data (General Data Protection Regulation — GDPR). We are giving you this information so that you know what personal data is shared when you agreed to being involved in the Children's Heart Study and your rights are under the law. This information is applicable to families who gave consent to be part of the cardiac impact study that included follow up phone calls over six months after the surgery only.

Sponsor Information

Great Ormond Street Hospital for Children NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and your child (name, contact details) in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Great Ormond Street Hospital for Children NHS Foundation Trust will keep identifiable information about you and your child for 18 months after the study has finished.

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 your rights, we will use the minimum personally-identifiable information possible. Our Data Protection Officer is Anna Ferrant, who can be contacted at your.data@gosh.nhs.uk

You can find more information on the study's website: gosh.nhs.uk/medical-information/clinical-specialties/cardi thoracic-surgery-information-parents-and-visitors/why-we-do-research/complications-after-heart-surgery-children

At your child's hospital

The Children's Heart research team at Great Ormond Street Hospital will collect information about you for from the Children's Heart study database at Great Ormond Street Hospital/ Bristol Children's/Birmingham Children's/Evelina London. This information will include your name, contacts and some

health information, which is regarded as a special category of information. We will use this information so that our researcher who is undertaking children's follow up assessments can contact you to arrange this for your child, with your agreement.

As described in the participant information sheet, any reports of analysed data will contain anonymous information only and this means it would not be possible to identify either you or your child.

What to do if you wish to make a complaint about how we have looked after your data

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) by post: Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF, online: ico.org.uk/concerns/ or by phone: 0303 123 1113.

Contact details and acknowledgements

You can read about this study in more detail here:

nets.nihr.ac.uk/projects/hsdr/12500506

gosh.nhs.uk/medical-information/clinical-specialties/cardi thoracic-surgery-information-parents-and-visitors/why-we-do-research/complications-after-heart-surgery-children

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Contact details:

If you would like further information about the study or wish to speak to someone about it, then please contact:

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Glasgow: children.heart@ggc.scot.nhs.uk

Appeal for help in fundraising

Can you help Great Ormond Street Hospital Children's Charity by featuring in a fundraising appeal?

GOSH Charity are looking for families and patients involved in the Children's Heart Study to take part in an exciting project for GOSH Charity.

We're working on a fundraising appeal which will be launched in February 2019. It will be sent to roughly 200,000 existing supporters via direct mail, email and social media, with the aim of raising £300,000 to support the hospital. £98,000 of money raised will be used to fund Dr Brown's new research study, which will explore ways to assess and help with child development in kids that have undergone heart surgery.

We're looking for a patient/family to support the appeal and bring our materials to life! You would be interviewed and take part in a photoshoot which would take around half a day (we'd visit you at your home for this). Our team would then create the marketing materials, working alongside you to ensure you're happy with what the charity send out.

We'd like to recruit a family who'd be happy to promote the appeal via their friends, family, colleagues and social media platforms in order to help the charity reach its fundraising goal and fund the continuation of this project.

If you're interested in being featured in this appeal, and supporting GOSH Charity, please contact Robert Butt, Donor Development Manager on 020 3841 3031 or via email at robert.butt@gosh.org

