Impact of the COVID-19 pandemic on outcomes of children with congenital heart disease who require cardiac interventions: the protocol

Completed protocol available at <https://hdruk.box.com/s/hmkiqfrt99u0s57c18e4ytpf6garb5t3>

This study is part of the main project in BHF data center, i.e., CVD-COVID-UK/COVID-IMPACT CCU007: Impact of COVID-19 pandemic on heart disease patients undergoing cardiac surgery.

## Aim

Children with complex congenital heart disease (CHD) require regular treatments during their lives, and remain vulnerable due to the consequences of CHD, with the highest risk period for mortalities and readmissions to hospital during the first year of life. There is currently very limited information available regarding how any impaired health care access and delays to treatment caused by the COVID-19 pandemic may have affected children with CHD, especially since their surgeries may be time critical. In this study, we aim to look for delays in the expected operative treatment pathway for children with complex CHD and to explore any increases in mortality and time spent in hospital during infancy, since these outcomes are associated with impaired access to treatment.

## Objectives

Study objectives are to

1. Create a patient-level cohort involving linked datasets related to children with complex CHD, i.e., patients who were born with and had an intervention for one of nine previously defined sentinel complex CHDs during the study period (see Table 1).
2. Identify all operations on the expected interventional treatment pathways applicable to each sentinel CHD diagnoses for all patients in the cohort (we define expected treatment pathways which involve a series of operations and were characterized in a previous study).
3. Define appropriate time eras to reflect health care service changes that span from before, during and after the COVID-19 pandemic.
4. Describe the timing of the series of operations on the planned treatment pathway for patients in the cohort within the specified pandemic related time eras, based on patient ages at each key surgery on the treatment pathway for each sentinel CHD type.
5. Compare the timing of each operation on expected planned series that children should receive based on their CHD diagnoses during the COVID-19 pandemic, with the timing of these operations before the pandemic when services were running normally, considering any variation related to clinical risk factors and social factors.
6. Describe study outcomes that may reflect health care access quality of ‘mortality at the age of 1 year and length of hospital stays in the first year of life’ for infants with complex CHD in the cohort, by sentinel CHD diagnoses.
7. Investigate the impact of the pandemic era on study outcomes, of mortality at the age of one year and the duration of inpatient hospital stays in the first year of life adjusted for clinical risk factors.
8. Investigate the role of the sex, ethnic group, deprivation, and any identified delays in planned treatment pathway procedures in determining the study outcomes, adjusted for case mix complexity.

## Deliverables

In terms of deliverables, we will

1. Report the ages at which children with the nine selected types of major CHD underwent the expected operations on their therapeutic pathway in the eras before the pandemic, during the pandemic restrictions and post the pandemic restrictions, flagging up any important differences.
2. Report the outcomes of mortality and length of hospital stay up to the age of 1 year by the nine major CHD diagnoses in the eras before the pandemic, during the pandemic restriction and post the pandemic restriction, flagging up any important differences.
3. Report any differences in treatment timing and key study outcomes based on social factors for children with the selected types of major CHD in infancy.

## Background

### Congenital heart disease (CHD)

CHDs affect approximately 5600 live-born children annually in England and Wales and is the commonest cause of infant death due to congenital anomalies in the United Kingdom (UK). 1 2 Annually, 7000-8000 paediatric cardiac procedures are undertaken in the UK, 58-60% of them in children under a year old. 3 Our population of interest, is children with major CHD meaning those who need to have cardiac surgery in infancy, since they are potentially most vulnerable to complications if they experience delays in their planned treatment. In very complex CHD, with only one functional ventricle, children need serial therapeutic interventions to achieve stable palliation consisting of at least two in infancy. 4 5 One-stage repair in infancy is standard practice for many CHD diagnoses with two functional ventricles 6 and more than one operation may be required for smaller or more complex patients 7 8 or as children grow. 9

### Later outcomes in complex CHD

In children undergoing paediatric cardiac surgery the early post-operative mortality rate is currently ~2%, 3 but higher for complex CHD when more challenging and high-risk operations are needed. 10 11 Our registry based study dated before the pandemic, which tracked infants undergoing cardiac interventions in England and Wales to 1 year post discharge; 12 13 and data from multi centre research in USA; 14 indicate that in infancy there is a significant risk of late death, after the immediate post-operative period, risk is higher when health care access is reduced 1 15 16 especially for complex CHD. 15

### Possible impact of delays in surgery and impaired care access

Paediatric cardiac operations can be truly lifesaving, but if they are undertaken at later than ideal ages due to delays in service provision, or if there is reduced access to other clinical services needed by these children, as has been reported by specialist cardiac centres during and immediately after the COVID-19 pandemic, then there is the risk that children’s outcomes could be worse. Given the complexity of these children, as well as early post-operative deaths, it is important to consider any deaths in the post-discharge period and deaths linked to subsequent interventions, therefore we need to look at their outcomes over at least a year to gain a fuller picture. If there are trends towards poorer outcomes this would be important to know, since it would inform efforts to improve services for these vulnerable children.

## Method

### Study design

Cohort study based on linked prospectively recorded electronic health record data.

### Data Sources

We use the following datasets in *NHS Digital:*

1. National Congenital Heart Diseases Audit (NCHDA) (the core dataset)
2. General Practice Extraction Service Data for Pandemic Planning and Research (GDPPR)
3. Hospital Episode Statistics (HES)
4. Death from Office of National Statistics (ONS)

### Data Management

NCHDA: The research analysis focuses on the NCHDA data with linkage to other important data sources available. This database was established after the Bristol Inquiry into Children’s Heart Surgery 17 by the Royal College of Surgeons to record and monitor the outcomes of paediatric cardiac surgery. 18 NCHDA data is of high quality, as evidenced by annual independent validation of children’s heart surgeries at all of the 11 specialistic centres in the UK. 3 It is important to acknowledge that CHD and paediatric cardiac operations are very diverse and complex 19-21, and are described in NCHDA using a special coding scheme called the International Paediatric Congenital Cardiac Code (IPCCC). 22 The specific primary CHD diagnoses 23 and paediatric cardiac operations are described in terms of their complexity or risk of death based on code combinations, using previously developed and tested methodology from our research group.10

Creation of the cohort: We use all NCHDA records of cardiac surgical procedures and interventional catheters performed in England between 1 January 2018 and 31 March 2023. Via the unique patient identifier, records in NCHDA are linked to: death registrations from the Office for National Statistics; General Practice Extraction Service Data for Pandemic Planning and Research (GDPPR); and Hospital Episode Statistics (HES) routine administrative data on inpatient, outpatient and accident and emergency (A&E) care at hospitals. All clinical data are organized into "care spells" that may include procedures, inpatient, outpatient visits, or A&E visits in any combination to manage overlaps in time frames24. We create a linked dataset at the patient level. For each patient, the dataset contains patient characteristics and survival status at patient-level, and cardiac procedure and hospitalization information at record-level.

### Selection of CHD diagnoses

In a prior research study called 'Congenital Heart Audit: Measuring Progress in Outcomes Nationally (CHAMPION),' funded by the Department of Health and Social Care's Policy Research Programme, we have selected a specific group of CHD diagnoses that best suited for long-term monitoring based on the input from clinicians, analysts, and patient families**.** In this study, we will include the CHD diagnoses that were selected as sentinel CHDs in CHAMPION because they are all major conditions that significantly affect young children, commonly requiring early intervention as neonates or infants for survival, commonly involving more than one procedure and are linked to mortalities in early life. These CHDs account for 40-45% of all children who are born with and start treatment for CHD in England and Wales: hypoplastic left heart syndrome (HLHS), functionally univentricular heart conditions (FUH, including double inlet left ventricle and tricuspid atresia), pulmonary atresia all types, transposition of the great arteries (TGA), tetralogy of Fallot, atrioventricular septal defect (AVSD, excluding partial AVSD which is treated in older ages), congenital aortic stenosis, coarctation of the aorta, and significant ventricular septal defect (VSD). Each of these CHDs had defined subgroups which are listed with the main sentinel CHD diagnoses in Table 1.

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| Table 1: Selected CHD diagnoses with subgroups. | |
| CHD diagnosis (in hierarchy) | CHD subgroup |
| Conditions that are exclusively single ventricle | |
| Hypoplastic left heart syndrome (HLHS) | HLHS |
| Functionally univentricular heart (FUH) | Double inlet ventricle |
| Tricuspid Atresia |
| Conditions with primary diagnosis that can be either managed by single ventricle or biventricular pathway | |
| Transposition of the great arteries (TGA) | Complex TGA & pulmonary stenosis (PS) |
| Complex TGA without pulmonary stenosis |
| TGA with intact ventricular septum |
| Pulmonary atresia | Pulmonary atresia & VSD |
| Pulmonary atresia with intact ventricular septum |
| Atrioventricular septal defect (AVSD\*) | Tetralogy with AVSD |
| Unbalanced AVSD |
| Complete AVSD |
| Conditions that exclusively biventricular | |
| Tetralogy of Fallot | Tetralogy absent pulmonary valve |
| Tetralogy with DORV |
| Standard tetralogy |
| Aortic Stenosis | Aortic stenosis with multi-level left heart obstruction |
| Isolated aortic stenosis |
| Coarctation | Coarctation plus VSD |
| Isolated coarctation |
| Ventricular septal defect (VSD) | Multiple VSDs |
| Isolated VSD |

\*we excluded partial AVSD because age at repair is well over 1 year old.

### Dataset inclusion and exclusion criteria

We include patients with one of these nine diagnoses of CHD defined in Table 1 who were born between January 2018 (start date selected to ensure complete procedure history was present) and March 2022 (end date selected to provide at least 1 year of follow up in all patients). We exclude patients from overseas, Scotland and Northern Ireland, because life status data are collected by ONS for patients from England and Wales only. We also exclude non-NHS patients and patients not linked to HES to ensure the complete procedure history and hospital utilization were present.

### Treatment pathways

Considering clinical views, related literature on interventional CHD treatment, data summaries for each CHD, and samples of unusual procedure histories, in our prior research we defined the expected interventional treatment pathways in terms of cardiac surgery, interventional catheters and hybrid types where applicable, for each sentinel CHD based on algorithms using diagnosis and procedure codes. There are two broad groups of cardiac interventional procedures: ‘reparative’ (in which an attempt is made to correct the heart defect in biventricular CHDs), and ‘palliative’ (in which a non-corrective procedure is undertaken in CHDs where repair is infeasible).

For functionally single ventricle CHDs (e.g. hypoplastic left heart syndrome (HLHS)), expected treatment pathway consists of a series of exclusively palliative procedures: ‘stage one procedures’, ‘stage two Glenn surgery’ and ‘stage three’ Fontan-type completion.25 We used previously defined interventional treatment pathway for functionally single ventricle heart disease26-28 to identify the expected treatment pathway for the selected sentinel CHDs with functionally single ventricle circulation. For this study we categorized procedures on the expected treatment pathway as palliative stage one procedures and stage two Glenn procedures.

In biventricular CHDs (e.g. tetralogy of Fallot), the expected treatment pathway involves a reparative surgery, and potentially also a ‘palliative stage one procedure’ usually undertaken in small babies to enable their circulation to support them until they grow large enough for a reparative procedure, e.g. systemic to pulmonary arterial shunt in tetralogy of Fallot followed by repair at a later procedure.29 We characterized the reparative surgeries and first stage procedures were for each selected biventricular sentinel CHD. For CHDs where a range of anatomy occurs and the treatment pathway may be either a biventricular repair or staged single ventricle palliation (e.g. in AVSD, since the CHD may present with ventricles that are either balanced or unbalanced in size)30: the treatment pathways were defined involving both palliative and reparative procedures.

Finally, treatment pathways may involve a ’pre-pathway procedure’ which is a short-term intervention that occurs after the child’s birth and before the first staged surgery (e.g.: balloon atrial septostomy in transposition of the great arteries (TGA)), which we defined drawing on peer reviewed definitions from prior studies. 26-28 These procedures were not counted in this study, and nor were reinterventions which are cardiac procedures that occur over and above the planned treatment pathway.

### Birth era

We define the following four birth eras based on the definition of pandemic periods used in previous works (Table 2). These time eras are based on those developed for project CCU07 question 1 and then further developed since this is a patient-based cohort study with a longer time horizon over which children were potentially exposed to a health care access problems over a period of time, with ascertainment of outcome after 1 year of life had elapsed.

* Pre-pandemic baseline: patients born from January 2018 to March 2019. Patients born during this era would not be expected to have any surgery during the pandemic and their care up to age 1 year was unaffected by the pandemic.
* Transition period: patients born from April 2019 to March 2020, during which they may be affected by delays in operations during their infancy because the pandemic started during the first year of their lives.
* Restriction period: patients born from April 2020 to June 2021 when there were a series of lockdowns and other social distancing measures were in place. We have collapsed the three restriction and corresponding relaxation periods due to relatively limited sample size.
* Post restriction period: patients born from July 2021 (when restrictions were eased) until March 2022 which is the latest feasible limit of the data sources. During this era the NHS was still under strain.

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| Table 2: Birth eras based on different phases of pandemic in England. | |
| Pandemic periods used in previous work | Birth eras used in this protocol(birth dates in NHS digital are only precise to mm/yy) |
| Pre-pandemic:  01 Jan 2018 to 22 Mar 2020 | Pre-pandemic baseline: patients born from Jan 2018 to Mar 2019 |
| Transition period: patients born from Apr 2019 to Mar 2020, during which they may be affected by delays in operations during their infancy. |
| First Restriction period:  23 Mar 2020 to 23 Jun 2020 | Restriction period: patients born from Apr 2020 to Jun 2021 when there were a series of lockdowns and other social distancing measures were in place. |
| First relaxation:  24 Jun 2020 to 04 Nov 2020 |
| Second restrictions:  05 Nov 2020 to 02 Dec 2020 |
| Second relaxation:  03 Dec 2020 to 05 Jan 2021 |
| Third restriction:  06 Jan 2021 to 21 Jun 2021 |
| Post third restrictions:  22 Jun 2021 to 31 Mar 2022 | Post restriction period: patients born from Jul 2021 (when the third restrictions were eased) until Mar 2022 which is the latest feasible limit of the data sources. During this era the NHS was still under strain. |

### Clinical factors

We consider the following clinical factors: major CHD diagnoses (and subgroups), congenital extracardiac comorbidities (eg, genetic syndrome, major congenital anomaly of any organ outside the heart), and prematurity (birth at gestation less than 37 weeks).

### Social factors

We consider the following social factors sex, deprivation based on index of multiple deprivation quintiles (IMD) and ethnicity based on broad ethnic groups used by NCHDA (given small numbers in fine NHS subgroups) white, Asian, black, mixed and other. We use either/both primary care and secondary care data to obtain those characteristics if missing in NCHDA for data completeness.

### Study outcomes

The primary outcome is the 1-year mortality rate, and the secondary outcome focuses on length of inpatient hospital stay before the age of 1 year. We will categorize hospital utilisation into three types: total (which includes inpatient, outpatient, and emergency care services), inpatient (inpatient care spells only), and outpatient (outpatient care spells only). This classification will offer a comprehensive view of the overall illness burden children face, including disease severity, surgeries, and complications after procedures.

## Statistical methods

#### Timing of operations on the expected CHD treatment pathway

Descriptive analysis - We report the age at occurrence of treatment pathway procedures (median and interquartile range) during the four separate birth eras (baseline, transition, restrictions, and post-restrictions), by CHD diagnoses including the subgroups. There are no accepted ‘gold standard’ ages at which these procedures must occur. Ages at treatment pathway procedures occur over age ranges in accepted practice, with variation in the range determined by clinical factors31. Therefore, in this study the age at treatment pathway procedures during the baseline period is the ‘proxy’ gold standard age for these procedures since this reflects an era when the service was running normally before any pandemic restrictions hit.

Modelling - We quantify the relationship between the exposure variable of birth era period (baseline, transition, restrictions, and post-restrictions) and the median age at pathway procedures using quantile regression, adjusted for clinical and non-clinical factors. For this analysis we grouped the pathway procedures to two types and ran two separate models. Groups were 1) palliative stage one procedure all CHD diagnoses, and 2) single ventricle palliative stage two procedures for f-SV CHDs and reparative procedure for biventricular CHDs. We selected these two groups because we considered that palliative first stage procedures are generally reasonably urgent and undertaken for critical neonatal CHD or for sicker infants with an unbalanced circulation and typically involve admission at birth / urgent admission and then early surgery, whereas single ventricle stage two and reparative procedures are more likely to occur planned manner after admission from home (although this is not always the case). We hypothesised that any delays in timing of surgery would be more likely in procedures that occurred outside the neonatal period with a typically planned admission (i.e.: in the second group of procedures). We test for any differences based on social factors by fitting multivariable linear regression models that incorporate interaction terms between birth eras and social factors (ethnicity, deprivation, and sex) for the outcome of median procedure age.

### Study outcome

Descriptive analysis

We ascertain study outcomes of mortality rate at 1-year using Kaplan-Meier by CHD diagnoses for children born in the eras of interest (baseline, transition, restrictions, and post-restrictions). We report length of hospital stay (total, inpatient and outpatient) by the age of 1 year for each of the nine CHD diagnoses, for children born in each of the eras of interest.

Modelling

Multivariable regression approach will be used to model the study outcomes, i.e., logistic regression is employed for infant deaths under the age of 1 year, and quantile regression is used for the median number of days spent at home before the age of 1 year (i.e., 365 days – total days spent in hospital as an in-patient; patients who died before the age of 1 year were assigned as 0 day at home as the worst outcome). The primary exposure is birth era (baseline, transition, restrictions, and post-restrictions), and covariates are sex, ethnicity, deprivation, CHD diagnosis, pre-term birth, and congenital comorbidity. If the birth era was found to be associated with procedure timing, then we will consider any delay in procedure timing as a mediating variable that influences the outcome. In all models, the between birth era and social factors (ethnicity, deprivation, and sex) are tested. The covariates may be collapsed if the numbers are too small within some categories for meaningful assessment of interactions.

## Patient and Public Involvement and Engagement (PPIE)

We worked with CHD user groups (Little Hearts Matter, the Children’s Heart Federation and for adults with CHD, the Somerville Foundation), and with patient co researchers affected by CHD, during 2022 and 2023, within the conduct of the research study ‘Congenital Heart Audit: Measuring Progress In Outcomes Nationally (CHAMPION)’ funded by the Department of Health and Social Care's Policy Research Programme. We held regular meetings with these individuals and groups in which we discussed the research and took their comments and feedback. We identified the nine CHD diagnoses of interest that are the focus of the current proposal during the CHAMPION project, by working with clinicians and with PPI advisors. They reached a consensus that the following issues were most important indicators: these CHD diagnoses were most common, the most likely to require one or more operations in infancy, and most likely to be linked to mortalities in affected patients.

Parents of children with CHD consider that delays to their children’s heart surgery and cancellations of their children’s heart surgery due to service pressures are extremely important and they believe that these should be a major focus of attention and improvement when they occur. We evidence this concern based on feedback from parents at the hospital trusts linked to the application and from CHD User groups such as Little Hearts Matter and the Children’s Heart Federation, and from an online discussion forum we undertook with parents and patients.32 The groups have a very strong interest in improved data and evidence about service provision and performance for children with CHD, as well as in the outcomes of these children at least a year old, thus considering not only the early post discharge outcomes but also later outcomes. Parents of children with CHD have reported that prolonged hospitalisation is linked to significant impacts on the child and family, as well as mental health and quality of life. A such the study outcomes in our proposal have taken on board this holistic feedback.

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