



**OUTCOMES FOLLOWING NEONATAL CARDIAC SURGERY IN  
CAPE TOWN, SOUTH AFRICA**

BY

DERRIK DU TOIT

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SUPERVISORS:

1. Professor L. Zühlke

Department of Paediatrics and Child Health, Red Cross War  
Memorial Children's Hospital

2. Associate Professor A. Brooks

Chris Barnard Division of Cardiothoracic Surgery, Groote Schuur  
Hospital

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## DECLARATION

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## **LIST OF ABBREVIATIONS AND ACRONYMS**

ASD	Atrial Septal Defect
ASO	Arterial Switch Operation
AVSD	Atrioventricular Septal Defect
BTS	Blalock-Taussig Shunt
CoA	Coarctation of the Aorta
CHD	Congenital Heart Disease
CPB	Cardiopulmonary Bypass
DSC	Delayed Sternal Closure
ECMO	Extracorporeal Membrane Oxygenation
IVS	Intact Ventricular Septum
IQIC	International Quality Improvement Collaborative
HIC	High Income Countries
HLHS	Hypoplastic Left Heart Syndrome
LMIC	Low and middle-income countries
LVOTO	Left Ventricular Outflow Tract Obstruction
MPA	Main Pulmonary Artery
PA	Pulmonary Artery
PDA	Patent Ductus Arteriosus
RACHS	Risk Adjustment for Congenital Heart Surgery
RCWMCH	Red Cross War Memorial Children's Hospital
RV	Right Ventricle
RVOTO	Right Ventricular Outflow Tract Obstruction
TGA	Transposition of the Great Arteries
TOF	Tetralogy of Fallot
VSD	Ventricular Septal Defect

## ABSTRACT

**Background:** Neonatal Cardiac Surgery has developed significantly since its advent, with improved outcomes, survival, and physiological repair. Limited programs offer neonatal cardiac surgery in emerging economies. We report our experience with neonates undergoing cardiac surgery in our cardiac surgery program.

**Methods:** We performed a secondary data analysis on all neonates aged  $\leq 30$  days undergoing congenital cardiac surgery from 1 April 2017 to 31 March 2020, including outcomes up to 30-days post-surgery.

**Results:** A total of 859 patients underwent cardiac surgery at our center, of these 81 (9.4%) were neonates. The proportion of neonates increased annually (8.7%, 9.6% and 10.2%). There were 49 (60%) males, and 32 (40%) had surgery in the second week of life. Fourteen (17%) were premature, four (5%) had a major chromosomal abnormality, five (6%) a major medical illness and eight (10%) a major non-cardiac structural anomaly. The RACHS categorization of surgery was predominantly RACHS 3; n = 28 (35%) and 4; n = 23 (29%). Hours in ICU were extensive; median 189 [IQR 114-286] as were hours of ventilation; median 95 [IQR 45-163]. Almost 60% (n=48) of procedures were complicated by sepsis, as defined in our database. The in-hospital mortality rate was 13% (n=13); the 30-day mortality rate was 19.8% (n=16).

**Conclusion:** The proportion of neonates in our service increased over the period. Focused strategies to shorten prolonged ICU stay and decrease rates of bacterial sepsis in neonates are needed. A multi-disciplinary, collaborative heart-team approach is crucial for best outcomes.

# CHAPTER 1

## Outcomes following Neonatal Cardiac Surgery in Cape Town, South Africa

Derrick du Toit, MBChB<sup>1</sup>, Lenise C Swanson, MBChB, MMed<sup>2</sup>, Shamiel Salie, MBChB, MPH<sup>1</sup>, Susan Perkins, MS<sup>2</sup>, Wisdom Basera, MPH<sup>3,4</sup>, John B Lawrenson, MBChB, MMed<sup>2</sup>, Thomas Aldersley, MBChB, MPH<sup>2</sup>, Andre Brooks, MBChB<sup>5</sup> and Liesl J Zühlke, MBChB MPH, PhD<sup>2,4,6</sup>

<sup>1</sup> Department of Paediatrics and Child Health, Red Cross War Memorial Children's Hospital, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa

<sup>2</sup> Division of Pediatric Cardiology, Department of Pediatrics and Child Health, Red Cross War Memorial Children's Hospital, Faculty of Health Sciences, University of Cape Town, Observatory, Cape Town, South Africa

<sup>3</sup> School of Public Health and Family Medicine, Faculty of Health Sciences, University of Cape Town, Observatory, Cape Town, South Africa

<sup>4</sup> South African Medical Research Council Francie Van Zijl Drive, Cape Town

<sup>5</sup> Chris Barnard Division of Cardiothoracic Surgery, Faculty of Health Sciences, University of Cape Town, Observatory, Cape Town, South Africa

<sup>6</sup> Division of Cardiology, Department of Medicine, Groote Schuur Hospital, Faculty of Health Sciences, University of Cape Town, Observatory, Cape Town, South Africa

Address for correspondence: Prof Liesl Zühlke Red Cross War Memorial Children's Hospital Institute of Child Health Building Room 2.17 Klipfontein Road Rondebosch Cape Town 7700 South Africa

Email:

liesl.zuhlke@uct.ac.za

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## INTRODUCTION

Congenital heart disease (CHD) is the most common birth defect, with a reported estimated global birth prevalence of 9.41/1000 and 2.31/1000 in Africa, with significant mortality and morbidity<sup>1,2</sup> The low prevalence in Africa may be due to underreporting and lack of prevalence studies.

Advances in surgical and medical management of children who have CHD have greatly improved overall survival and decreased the long-term sequelae of cardiac surgery. However, there are still significant differences in mortality rates between low and middle-income countries (LMICs) (13.5%)<sup>3</sup> and high income countries (HICs) (6.9%).<sup>3,4</sup> As morbidity has decreased and survival has increased over the past two decades, surgery on neonates has evolved, including preterm, low-birth weight or infants under one kilogram. The previous approach of performing mostly palliative surgeries in the neonatal population has now been overtaken by a norm of surgical procedures aimed at complete repair, with huge advancements made in intensive care, surgical and post-operative practices.

Neonates are a vulnerable patient group as they are still transitioning from intrauterine to extrauterine life. They include a wide range of gestational and postnatal ages, each with differing levels of maturity of the cardiovascular system.<sup>5</sup> Furthermore, immaturity of other organ systems can contribute to complex patient scenarios, with a higher risk

of developing sepsis, lung immaturity which may necessitate prolonged ventilatory requirements, relative gut immaturity and haemodynamic instability.

Various factors contribute to outcomes post-cardiac surgery. In a single centre study assessing outcomes in cardiac surgery in patients weighing less than 2,8 kilograms, lower gestational age at birth was found to be a major independent risk factor for early mortality.<sup>6</sup> Costello et al concluded that optimal early outcomes were associated with term delivery at 39 to 40 weeks.<sup>7</sup> Preterm and low birth-weight patients had twice the relative risk of developing complications and six times the risk of mortality following cardiac intervention compared to a matched population.<sup>8</sup>

The International Quality Improvement Collaborative (IQIC) was launched in Geneva in 2007 to benchmark and support cardiac centers in LMICs countries.<sup>9</sup> Studies looking at the impact of IQIC have shown significant improvements in key outcome measures such as surgical site infection, length of ICU stay, rates of bacterial sepsis<sup>10</sup>, as well as improved post-surgical outcomes.<sup>11</sup> Sub-analyses of local IQIC data have shown significant improvement in outcomes by implementing low-cost and low-resource interventions such as effective communication and teamwork.<sup>9</sup>

Red Cross War Memorial Children's Hospital (RCWMCH) is the only public service tertiary center undertaking congenital cardiac surgery on children in the Western Cape Province. All children requiring congenital cardiac surgery presenting to the Western Cape's other public tertiary referral hospitals are referred to RCWMCH. Patients are

also referred from peripheral hospitals and the Eastern and Northern Cape Provinces. Data capturing and recording on pediatric cardiac surgical patients in to the IQIC project began at RCWMCH in 2017.

There are little data on neonatal cardiac surgery in the African context as this is rarely performed outside of specialised units in South Africa, Northern Africa (Tunisia, Morocco, Algeria) and Egypt.

We therefore describe demographic and clinical features of neonates undergoing cardiac surgery over the three year prior to COVID-19 and report their diagnoses, surgical procedures, and outcomes.

## METHODS

We conducted a retrospective database and chart review at RCWMCH. Children aged  $\leq 30$  days undergoing congenital cardiac surgery at RCWMCH over a three-year period from 1 April 2017 to 31 March 2020 were enrolled. This period was selected to avoid the COVID-19 related restrictions on cardiac surgery. Data were extracted from the IQIC database and hospital records as required and included patient outcomes up to 30-days post-surgery. Patients that were not contactable at 30-days were deemed as lost to follow up. Data were collected using the Case Report Form in Appendix 1 and Table 1 describes surgical variables and outcomes captured. Ethics approval for the study (HREC 872/2019) was obtained from the University of Cape Town (UCT)

Human Research Ethics Committee with a waiver of parental consent. A REDCap™ database hosted on a UCT-secured server was used for recording and managing data.

## STATISTICAL ANALYSIS

Descriptive statistics were used to describe the categorical and continuous variables, such as frequencies and medians. Continuous data was reported as medians and interquartile range (IQR) and categorical data as proportions. Data were stratified by vital status (alive or demised) and the association with the demographic and clinical information was tested using Fisher's exact or chi-square for categorical variables, and Mann Whitney test for continuous variables. Stata 16<sup>12</sup> was used for analysis. The value for statistical significance was set at p-value < 0.05.

## RESULTS

In the study period, 859 children underwent congenital cardiac surgery at RCWMCH. Of these, 81 (9.4%) were neonates. Table 2 further describes these neonates according to clinical presentation and socio-demographic variables stratified by vital status. The proportion of neonatal procedures performed increased yearly over the study period (Figure 1). Sixty percent of neonates were male. Close to three quarters of neonates were classified as having normal nutritional appearance. The vast majority had a WHO weight for age percentile above the 15<sup>th</sup> percentile. The most common preoperative procedure required was the use of inotropes and balloon atrial septostomy. Close to 35% (8/23) of patients with a diagnosis of Transposition of the

Great Arteries (TGA) underwent a balloon atrioseptostomy. 17% of the cohort were premature. There were no statistical differences between the groups in terms of age at surgery, sex, nutritional appearance, preoperative procedures, or prematurity.

The most common anomalies were Transposition of the Great Arteries with Intact ventricular septum (TGA IVS), TGA Ventricular Septal Defect (VSD), coarctation of the aorta and hypoplastic arch, and Truncus Arteriosus. Almost ten percent of cases had a major non-cardiac structural anomaly. Most neonates (40%) were operated on during the second week of life. Most neonatal surgeries were classified as being Risk Adjustment for Congenital Heart Surgery (RACHS) category three and four (III n = 28, 35% and IV n = 23, 29%) (Figure 2), with one case classified as RACHS 5. Figure 3 lists the diagnoses of the neonates operated on during the study period.

Table 3 describes the surgery undertaken as well as other related parameters. A total of thirteen patients (16%) had an open chest after theatre, 38% in those who died and 11% in those that survived ( $p = 0.01$ ). Median days from procedure to hospital discharge was 16 [10-22]. Median ICU stay in hours amounted to 189 [114-286]. Mean ventilation time in hours was 95 [45-163]. There were no cardiopulmonary bypass perfusion events.

40% of patients developed surgical site infections and 59% of neonates were identified as having bacterial sepsis (Table 4). A quarter of organisms identified were Klebsiella,

with no organism identified in 46% of cases. No organism was identified in 70% of cases of neonates who died with bacterial sepsis.

In hospital mortality rate was 16% (n=13); there were an additional three deaths in those who were discharged from hospital leading to a 30 day follow up mortality rate of 19.8% (n = 16). A total of thirteen patients were lost to follow up with respective rates of 13% (April 2017- March 2018), 15% (April 2018 – March 2019) and 38% (April 2019 – March 2020) in the study period.

## DISCUSSION

Neonatal cardiac surgery is the most demanding cardiac surgical competency, not only technically very demanding but requiring a very high level of skill and demand on perfusion and ICU care. Our center is one of the few offering this service in our country in the public service; very few others exist on our continent. Almost 10% of patients operated upon during our study period were neonates, increasing slightly each year. We found that neonates had prolonged ICU stays and acquired multiple infections. Secondly the vast proportion of these cases were classified as RACHS 3 or RACHS 4. Thirdly the mortality rate was substantial (16% for in-hospital mortality and 19.8% for 30-day mortality). These rates were comparable with international data which ranged from 11% to 18%<sup>13-16</sup>.

Almost 10 % of cardiac surgeries were on neonates during our study period. A review of a decade of neonatal cardiac surgery from Israel reported that neonates constituted 22.5% of all cases performed at their unit.<sup>17</sup> Bobillo-Perez et al from Spain reported a similar proportion (18%)<sup>18</sup> which is most likely due to better resourced environments , well-developed referral processes as well as antenatal diagnoses and directed deliveries of complex patients. These programs are substantially different to our program, as the only public service unit providing cardiac surgery to a large catchment area, in the context of resource constraints. A LMIC program from India also reported a high proportion of neonates (21%)<sup>19</sup>, but this program is now a center of excellence for the region with screening for critical CHD (CCHD) and rapid transfer of patients into the center.<sup>20</sup> We anticipate that as improved referrals, ante-natal diagnoses and awareness of CCHD increases, our neonatal case-load will also increase. More vigorous epidemiological research is needed with regards to CHD in southern Africa, to formulate prevention strategies and improved antenatal and postnatal screening practices.<sup>21</sup> Local studies have shown the effectiveness and high specificity of offering pre discharge pulse oximetry screening to newborns in diagnosing cases of CHD (and more so CCHD).<sup>22</sup> However, pulse oximetry screening is not yet routinely available, which contributes to late presentations, often outside of the neonatal period.

Most neonates were operated on during the second week of life, in part due to delayed post-natal presentation or postponement of surgery due to suspected infection.

Our center lies within a combined medical and surgical ICU with dedicated cardiac beds, with a multi-disciplinary heart team, and is well-resourced in comparison with

other countries on the continent with expertise in surgical and post-surgical strategies. However, several resources such as ECMO or Left Ventricular Assist Devices (LVADs) are still under severe restriction based on our conflicting ICU priorities. As referrals increase, and to operate on all referred patients in an acceptable time frame, we have to prioritise strategies such as a geographically separate cardiac ICU area, highly stringent infection control and dedicated cardiac ICU staff.

The only predictor of mortality in our cohort was an open chest after surgery (38% versus 11%). In the entire cohort, 16% required delayed sternal closure (DSC) after surgery. DSC is required when patients exhibit hemodynamic and respiratory instability postoperatively<sup>23</sup> and has been associated with prolonged ICU and hospital stay<sup>24</sup>. Our program practices DSC selectively and thus it should be seen as a surrogate for the most critical patients. Patients that have necessitated DSC require more labour-intensive nursing resources such as one on one nursing with even more stringent infection control measures being of the utmost importance.<sup>23</sup> The proportion of DSC is thus an important indicator of a challenging intra and post-operative course.

In total, 59% of neonates in this cohort had bacterial sepsis; either preoperative (along with possible nosocomial organisms from referral centres), or postoperative (hospital acquired infections such as Klebsiella).<sup>25</sup> Most organisms isolated were Gram negative Klebsiella, although in 70% of neonates who died no organism was identified. We noted no congruence between surgical pathologies and organisms isolated. Gram negative organisms are becoming increasingly predominant in neonatal sepsis in

LMICs (up to 60% of cases).<sup>26</sup> Ensuring that preoperative candidates have been treated for community acquired or hospital acquired sepsis before undertaking surgery can improve postoperative outcomes. Moreover, stringent infection control measures are of paramount importance as the hands of healthcare workers are said to be the most common iatrogenic cause of hospital acquired infections in neonates.<sup>27</sup> A previous study from our unit demonstrated the incomplete application of sternal wound prevention bundle checklists in improving quality practices.<sup>28</sup> In addition, antibiotic stewardship in this regard is of great importance to curb the further development of multi drug resistant organisms.

Elassal et al identified factors that were associated with prolonged hospital stay – namely older age at surgery (noting that most of our patients were operated during the second week of life), smaller body weight, lower birth weight, prematurity, higher RACHS-1 score and necrotising enterocolitis (NEC).<sup>15</sup> The patient (Annexure Table 1 Patient number 2) with the longest ventilation time was ventilated for a total of 834 hours with a total ICU stay of 39 days and demised on day 50 of life. Although not a predictor of mortality in our patients, the prolonged ventilation times raise concerns about possible neurodevelopmental outcomes, and sequelae such as subglottic stenosis or need for tracheostomy, ventilator-associated nosocomial pneumonias or baro- and volutrauma. Focused strategies to shorten the duration of ICU stay are needed such as improving early identification and treatment of sepsis, improved screening antenatally (i.e. neonates not presenting to our unit in extremis) and training and education of nursing staff, doctors, and surgeons.

Close to ten percent of our cohort (8 neonates) had a concomitant major non-cardiac structural anomaly (Table 5). These could have complicated intra- and postoperative courses resulting in longer ICU and/or hospital stays.

Initially two CPB events were noted. We adjudicated the events; on review these did not meet the IQIC definition. In comparison, Stammers et al out of Canada reported an incident rate of one in every 83.9 performed cases in their paediatric population.<sup>29</sup> Our service has prioritised heart-team staff development (ICU doctors and nurses, cardiothoracic surgeons, cardiologists, physiotherapists, clinical technologists as well as perfusionists) and adopting neonatal brain protection strategies, to avoid injuries resulting in worsened neurodevelopmental outcomes in various developmental domains.<sup>30</sup>

Jenkins et al developed the RACHS Score in 2002. Their aim was to develop a method to adjust for baseline risk differences and permit statistically significant comparisons of in-hospital mortality for children undergoing surgery for CHD.<sup>31</sup> The RACHS score was further modified in 2017 to include those undergoing surgery outside of the neonatal period (RACHS-2).<sup>32</sup> In 2022, RACHS-2 was updated further to RACHS-3 in order to strengthen the comparison between surgical procedures.<sup>33</sup> The Aristotle score and the STS-EACTS score are alternative means of stratification of complexity in congenital heart surgery.<sup>16</sup> We describe one RACHS 5 diagnosis (Truncus arteriosus with an interrupted aortic arch addressed by end-to-end anastomosis and right ventricular

outflow tract reconstruction). Two-thirds of patients were classified RACHS 3 to 4, demonstrating sufficient complexity and our preferred approach of definitive repairs in neonates. The RACHS categories did not prove to be of significance – which suggests that other factors like delay in surgery as well as bacterial sepsis play more important roles. We could not identify surgeries that put neonates at risk more than others. We furthermore note that there was a statistically significant difference between those alive and dead who had undergone arterial switches with VSD closure – but in real terms this difference was only one patient.

We recorded an in-hospital mortality rate of 16% and 30 day-mortality of 19.8%, which is only slightly higher than other international centers,<sup>13,15,34</sup> while our overall mortality rate for our program was 5% in this period. Elassal et al from Saudi Arabia recorded an overall mortality of 11%, which is slightly less than the mortality reported in the STS database (12.2%) and EACT-database (13.3%).<sup>15</sup> Comparative in-hospital mortality rates of 14% were observed in the program in India.<sup>14</sup> However, this reported on neonatal cardiac surgery in low birth weight infants only. In 2009 our surgical program adopted the preferred approach of definitive surgery; however, we do not undertake surgery on hypoplastic left heart syndrome as we have adopted a strategy of best evidence for outcomes where the mortality rates and required resources are too high. The costs of neonatal ICU stay amount to \$1805 per day in a Canadian study<sup>35</sup>, these costs are exorbitant for emerging economies and therefore cases need to be prioritised.

We noted with concern the high rates of loss to follow-up in 2019-2020, which could be due to COVID-19 and an 8-week country-wide lockdown commencing March 2020. However, we continue to use IQIC and other patient-centred strategies to decrease this proportion. We have instituted a patient-held card to identify patients as belonging to the cardiac service, with diagnosis and contact numbers as well as high-risk clinic for specific follow-up at 6 weeks post-op and beyond.

Developing, staffing, and maintaining a high-volume neonatal cardiac surgery program in Africa is complex, for several reasons. There is a high under-5 mortality rate in most countries on our continent, including South Africa, with infections and prematurity the leading cause of death in these infants.<sup>36</sup> LMICs have a significant burden of hospital acquired infections, which complicates the post-operative period.<sup>37</sup> Human resources for health are concerning, with few programs to train allied professionals, nursing shortages and only small teams/individual cardiac specialists in several countries. Finally there are very few fellowship or training opportunities on the continent for congenital surgeons.<sup>38</sup> Possible solutions to address these inadequacies in South Africa include strengthening cardiac services in the country and the creation of surgical units in other provinces. Opportunities in terms of private/public partnerships should be considered.

Ongoing training and empowering of nursing staff involved in the care of patients undergoing surgery for CHD, along with a heart team-based approach, leads to substantial improvements in bacterial sepsis and surgical site infections.<sup>9,11</sup> NGOs

such as Children's HeartLink are paramount in addressing the disparities that exist with regards to access to congenital cardiac surgery in those countries with limited resources.<sup>39</sup>

## LIMITATIONS

Since this is a single centre study our findings are specific to the Western Cape, these results do not represent the situation in the rest of the country, nor outcomes and characteristics of neonates operated in private hospitals. Due to the late presentation of patients referred to us (logistical, screening, or patient optimisation factors), a large proportion of children with cardiac diagnoses that require intervention in the neonatal period do not get operated on before thirty days of age. In addition, our study would have been strengthened by longer follow up times. This would have enabled us to explore neurodevelopmental outcomes as well as the existence of any remaining morbidity. Moreover, longer follow up times will give insight into data not influenced by COVID, which is more representative of the usual surgical program. IQIC does not routinely collect information regarding viral infections or noting of antibiotic administration prior to surgery, this should be considered for inclusion into future surgical registries. A single center retrospective cohort study done in Australia showed that 8.2% of neonates enrolled tested positive for a viral infection. These infections were associated with prolonged postoperative cardiac surgical recovery.<sup>40</sup> It should be noted that the IQIC database does not differentiate at which point patients initially develop bacterial sepsis. Lastly, as the study used a pre-existing database to collect

data prospectively, we relied on the accuracy of those collecting the data. Moreover, information required with regards to certain patients that demised was not available from medical records.

## IMPLICATIONS FOR FUTURE RESEARCH AND CLINICAL PRACTICE

We describe the experience from one of the few cardiac surgery units in Africa performing neonatal cardiac surgery. While we demonstrate growing expertise and comparable improved outcomes, we have identified areas for improvement in the program. Geographical separation of patients undergoing cardiac surgery in the ICU away from the general ICU patient can decrease rates of sepsis, along with a stronger focus on basic infection control measures and concomitant formation of a comprehensive and dedicated cardiac team. Although we currently have a multi-disciplinary team, not all members are dedicated only to cardiac patients e.g. rotating fellows, residents and nursing staff. An American single centre study looking at the outcomes of changing to a dedicated cardiac ICU, showed significant improvement in the rates of wound sepsis, emergent resuscitation as well as mortality.<sup>41</sup>

Future research should include extending follow up times and assessing medium to long-term neurodevelopmental outcomes. An Infant Neurodevelopmental assessment at twenty weeks corrected gestational age and long-term follow up to assess school performance could provide more granular assessment of morbidity in this population. Further strategies are needed to shorten ICU stay which will lead to improved

outcomes. The use of sternal wound prevention bundles has been shown to decrease rates of sternal wound infection in delayed sternal closure.<sup>42</sup> Decreasing rates of bacterial sepsis, especially hospital acquired, and gram-negative sepsis will also lead to improvements in morbidity and mortality. The complex associations between sepsis and neonatal cardiac surgery specific to the LMIC context should be explored further. Moreover, more research is needed to delineate the exact extent of the impact on CHD in Africa in preventative and treatment programs. These programs should then be aligned with local resources with the goal of maintenance and expansion.<sup>38</sup>

## **CONCLUSION**

Neonates undergoing cardiac surgery represent the pinnacle of cardiac surgery: we describe high rates of bacterial sepsis in these patients, especially gram-negative septicaemia, long ICU stays and long ventilation times. However, our 30-day mortality rate of 16% is comparable with international standards. We identified one independent risk factor for mortality - open chest after surgery. This can serve as an important predictor of high-risk patients, while stringent measures to curtail infections are of paramount importance.

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# TABLES

Table 1: Surgical variables and Outcomes

Surgical variables	Outcomes
Preoperative procedure	In-hospital death
Description of surgical procedure	Number of days from procedure to discharge
Palliative versus repair procedure	ICU stay in minutes and hours
Number of operations or reoperations prior to surgery	Ventilation time in hours
Open chest after surgery	CPB events
Need for additional surgery for bleeding	Surgical site infection
RACHS score	Bacterial sepsis
	Alive at 30 days post-surgery

Table 2 Clinical presentation and socio-demographic variables stratified by vital

status

<b>Variable</b>	<b>Total N=81</b>	<b>Died N=16</b>	<b>Alive N=65</b>	<b>Fisher's Exact test p-value</b>
<b>Clinical presentation and demographics</b>				
<b>Age at surgery</b>				
Week 1	14 (17)	0	14 (22)	<b>0.05</b>
Week 2	32 (40)	10 (63)	22 (34)	
Week 3	13 (16)	1 (6)	12 (18)	
Week 4	22 (27)	5 (31)	17 (26)	
<b>Sex</b>				
Female	32 (40)	7 (44)	25 (38)	0.70 #
Male	49 (60)	9 (56)	40 (62)	
<b>Nutritional appearance</b>				
Normal	59 (73)	11 (69)	48 (74)	0.80
Malnourished	21 (26)	5 (31)	16 (25)	
Emaciated	1 (1)	0	1 (2)	
<b>Preoperative procedures</b>				
Balloon atrial septostomy	9 (11)	1 (6)	8 (12)	0.68
Resuscitation	3 (4)	0	3 (5)	1.00
Inotrope therapy	9 (11)	0	9 (14)	0.19
Ventilation preoperatively	6 (7)	0	6 (9)	0.59
No preoperative procedure reported	64 (79)	15 (94)	49 (75)	0.17 #

<b>Prematurity</b>	14 (17)	3 (19)	11 (17)	1.00
<b>WHO Weight/BMI for Age percentile</b>				
N <sub>1</sub> =56; N <sub>2</sub> =13; N <sub>3</sub> =43				
<5 <sup>th</sup> percentile	11 (20)	2 (15)	9 (21)	0.74
≥5 <sup>th</sup> , <15 <sup>th</sup> percentile	3 (5)	0	3 (7)	
≥15 <sup>th</sup> percentile	42 (75)	11 (85)	31 (72)	

- p-value of ≤0.05 considered statistically significant.
- proportions (%) reported as n/N (except if data is missing denominator added in the variable name column)
- p-values derived using Fisher's Exact test.
- # p-values derived using Chi-square test.

Table 3: Surgery undertaken as well as other related parameters

<b>Variable</b>	<b>Total N=81</b>	<b>Died N=16</b>	<b>Alive N=65</b>	<b>Fisher's Exact test p-value</b>
Operations or reoperations before surgery	1 (1)	0	1 (2)	1.00
Open chest after surgery	13 (16)	6 (38)	7 (11)	<b>0.01 #</b>
Required additional surgery for bleeding	2 (2)	0	2 (3)	1.00
<b>RACHS-1 Risk category</b> N <sub>1</sub> =79; N <sub>2</sub> =16; N <sub>3</sub> =63				
1	1 (1)	0	1 (2)	0.20
2	26 (33)	4 (25)	22 (35)	
3	28 (35)	4 (25)	24 (38)	
4	23 (29)	7 (44)	16 (25)	
5	1 (1)	1 (6)	0	
<b>Risk category 1</b>				
Atrial septal defect surgery	1 (100)	0	1 (100)	-
<b>Risk category 2</b>				
Pulmonary outflow tract augmentation	2 (8)	1 (25)	1 (5)	0.29
Ventricular septal defect repair	1 (4)	0	1 (5)	
Coarctation repair	19 (73)	2 (50)	17 (77)	
Pulmonary valvotomy or valvuloplasty	1 (4)	0	1 (5)	
Total repair of Tetralogy of Fallot	1 (4)	1 (25)	0	
Vascular ring surgery	1 (4)	0	1 (5)	
Repair of aorto-pulmonary window	1 (4)	0	1 (5)	

<b>Risk category 3</b>				
Pulmonary artery band	3 (11)	0	3 (13)	0.08
Systemic to pulmonary artery shunt	7 (25)	3 (75)	4 (17)	
Arterial switch operation	18 (64)	1 (25)	17 (71)	
<b>Risk category 4</b>				
Repair of total anomalous pulmonary veins	6 (26)	0	6 (38)	0.08 #
Arterial switch operation with VSD closure	8 (35)	5 (71)	3 (19)	
Repair of truncus arteriosus	8 (35)	2 (29)	6 (38)	
Repair of hypoplastic or interrupted arch with or without VSD closure	1 (4)	0	1 (6)	
<b>Risk category 5</b>				
Repair of truncus arteriosus and interrupted arch	1 (1.2)	0	1 (1.5)	0.36
Days from procedure to discharge, median (IQR)	16 (10-22)	17 (9-70)	15 (10-22)	0.65 *
ICU stay (hours), median (IQR)	189 (114-286)	243 (91-332)	169 (114-284)	0.47 *
Ventilation time (hours), median (IQR)	95 (45-163)	181 (72-250)	92 (44-147)	0.07 *

- p-value of  $\leq 0.05$  considered statistically significant and derived using Fisher's Exact test.
- Continuous data reported as median (Interquartile range - IQR)
- \* p-values derived using Mann Whitney U-test.
- # p-values derived using Chi-square test.
- Proportions (%) reported as n/N

Table 4: Surgical site infections and bacterial sepsis

	<b>Total N=81</b>	<b>Died N=16</b>	<b>Alive N=65</b>	<b>Fisher's Exact test p-value</b>
Surgical site infection	32 (40)	4 (25)	28 (43)	0.19 #
Bacterial sepsis **	48 (59)	10 (63)	38 (58)	0.77 #
<b>Organisms isolated</b> N <sub>1</sub> =48; N <sub>2</sub> =10; N <sub>3</sub> =38				
Klebsiella	12 (25)	2 (20)	10 (26)	0.95
PSA	3 (6)	0	3 (8)	
Serratia marcescens	3 (6)	1 (10)	2 (5)	
Acinetobacter baumannii	1 (2)	0	1 (3)	
Acinetobacter and Klebsiella	1 (2)	0	1 (3)	
Bacillus	1 (2)	0	1 (3)	
Enterobacter Cloacae	1 (2)	0	1 (3)	
Enterococcus	1 (2)	0	1 (3)	
MRSA	1 (2)	0	1 (3)	
Strep G	1 (2)	0	1 (3)	
No organism isolated	22 (46)	7 (70)	15 (39)	
<p><i>** IQIC definition of bacterial sepsis: known or presumed bacterial sepsis with fever or hypothermia, tachycardia, hypotension, tachypnea, leukocytosis or leukopenia. Positive blood cultures are not required if the patient's clinical course is otherwise consistent with sepsis, because of the possibility of false negatives. Bacterial sepsis, secondary to other infections such as pneumonia, catheter associated bloodstream infections, or surgical site infections should be included<sup>9</sup>.</i></p>				

- p-value of  $\leq 0.05$  considered statistically significant and derived using Fisher's Exact test.
- proportions (%) reported as n/N (except if data is missing denominator added in the variable name column)
- # p-values derived using Chi-square test.

Table 5: Non-cardiac structural anomalies (n=8)

<b>CARDIAC DIAGNOSIS WITH ASSOCIATED ANOMALIES</b>	
1. Coarctation of the aorta	Congenital chylothorax, hydronephrosis
2. DORV/AVSD/Hypoplastic LV/Common atrium (Isomerism)	Asplenia
3. Double aortic arch	Tracheomalacia
4. PA/VSD/PDA/MAPCA	Cleft palate
5. Tetralogy of Fallot	Cleft lip and palate
6. TGA ASD VSD PDA	Absent corpus callosum, microcephaly, cleft lip and palate
7. TGA	Ectopic kidney
8. Truncus arteriosus	Vertebral anomalies

Abbreviations: ASD, Atrial Septal Defect; AVSD, Atrioventricular Septal Defect; DORV, Double Outlet Right Ventricle; LV, Left Ventricle; MAPCA, Major Aortopulmonary Collateral Artery; PA, Pulmonary Atresia; PDA, Patent Ductus Arteriosus; TGA, Transposition of the Great Arteries; VSD, Ventricular Septal Defect

# FIGURES

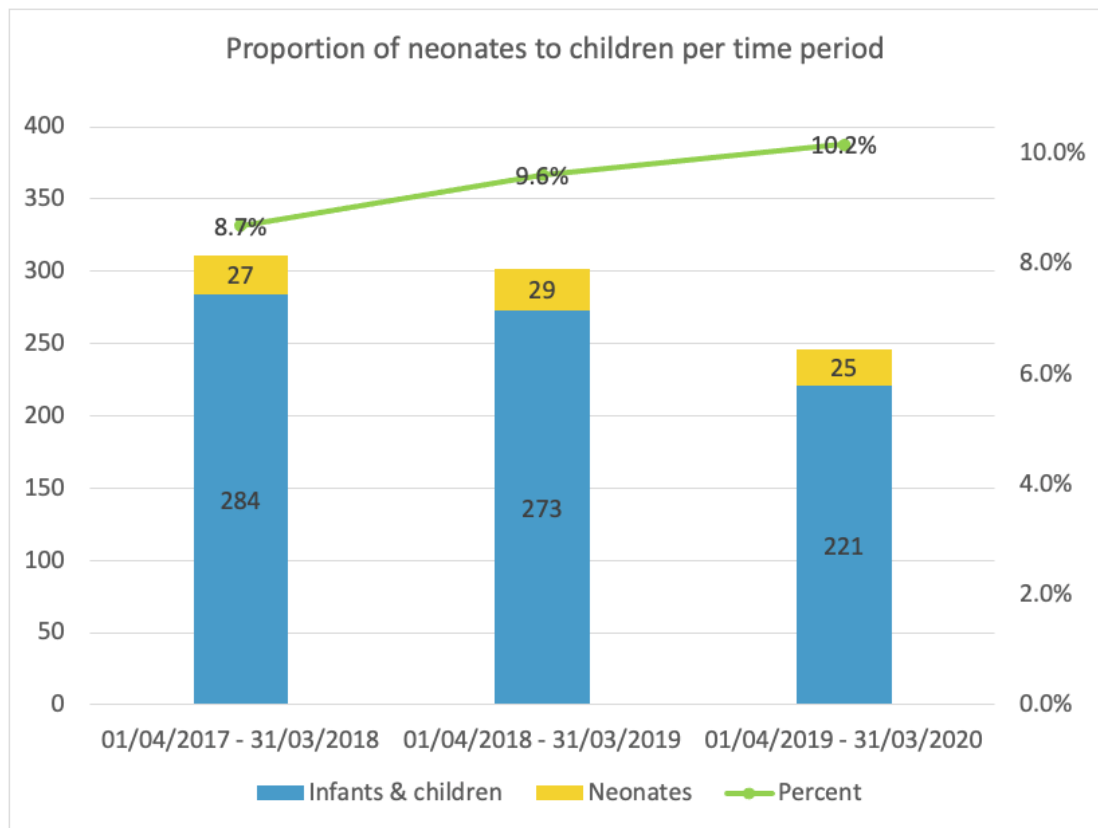


Figure 1 Proportion of neonates in the three-year period.

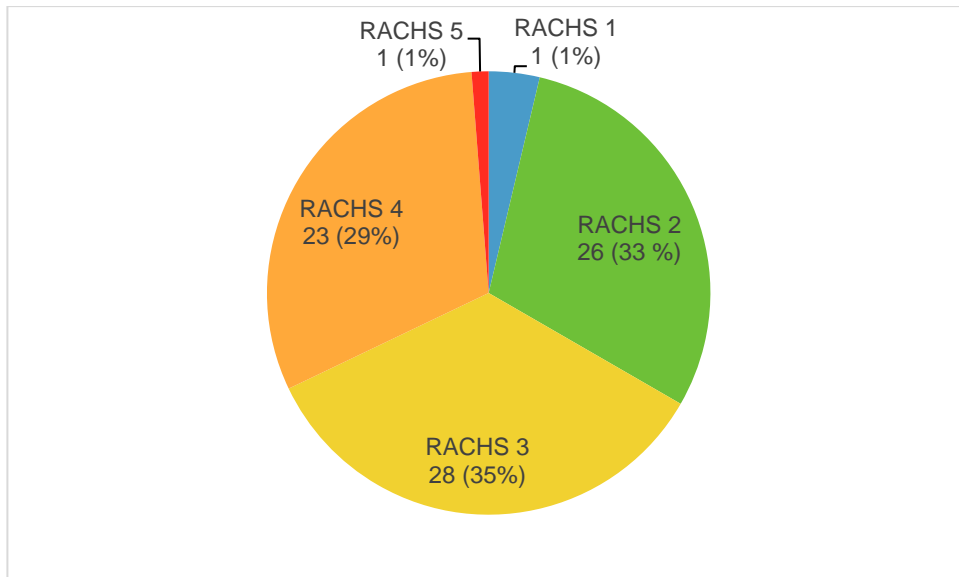


Figure 2: Distribution of RACHS scores

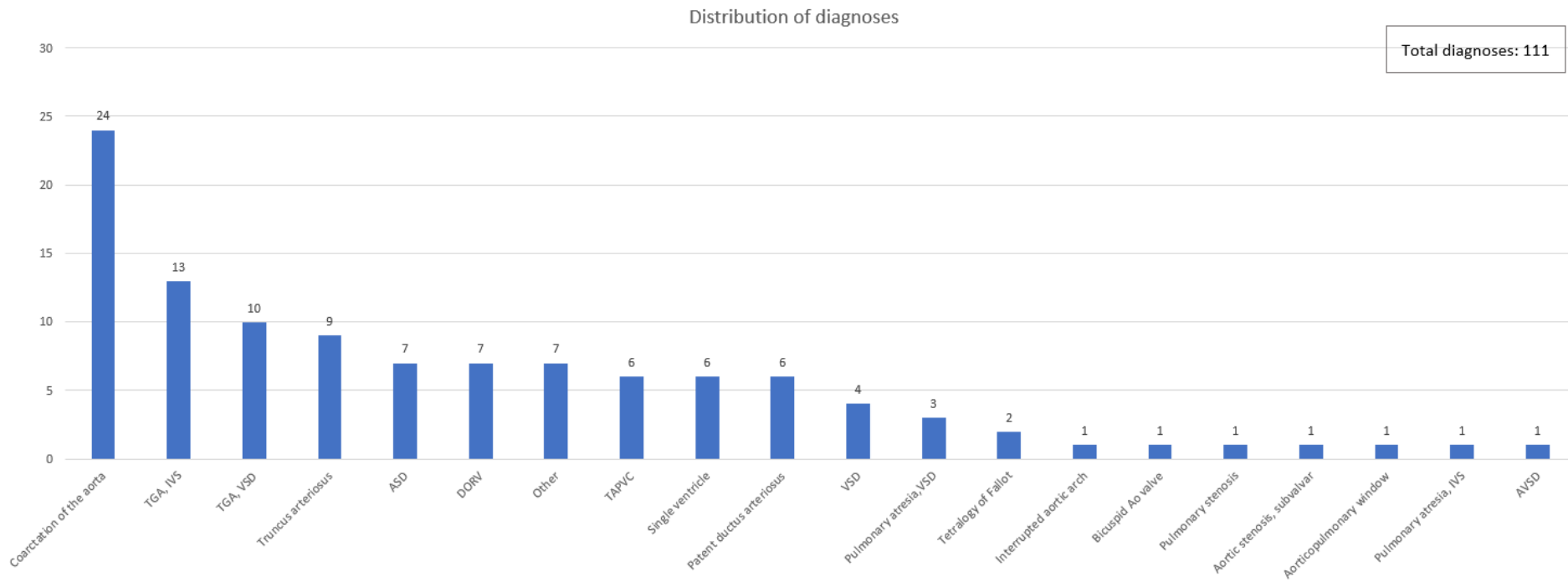


Figure 3: The distribution of diagnoses for CHD patients undergoing surgery in the neonatal period at RCWMCH, between 1 April 2017 to 31 March 2020. Multiple diagnoses were permitted per patient.

# ANNEXURE

Table 1: Summaries of in- hospital mortality

	Gestation in weeks/sex/weight	Echo and diagnosis	Associated conditions	Operation	Course in theatre/ICU and cause of death
1	34W Male 2400g	Truncus arteriosus type 1, VSD, RPA stenosis	?VACTERL association with single umbilical artery, vertebral anomalies	ASD created and left open. VSD closed. RVOT reconstructed.	Surgery on day 24 of life. Poor RV function successfully weaned off CPB with nitric oxide. Ventilation problematic, no improvement with manual ventilation and endotracheal tube change. Died on table in theatre at end of procedure.
2	37W Female 2380g	DORV with sub-pulmonic VSD (Taussig-Bing), coarctation of the aorta with hypoplastic transverse arch, abnormal coronaries with RCA coming		PDA ligation, augmentation of hypoplastic arch, VSD closure,	Multi-organ dysfunction in postop period with ARDS/renal failure/coagulopathy ESBL Klebsiella Pneumonia Bacteraemia. Arrhythmias – AV block and SVT, Fungal sepsis, Bilateral Grade 3 IVH with ventricular

		off LCA (single left ostium), PDA		arterial switch with LeCompte manoeuvre, ASD stitch closure	dilatation and subclinical seizures, Sternal wound sepsis.
3	40W Male 3300g	TGA, ASD, PDA, perimembranous VSD		ASO, VSD repair. LeCompte maneuver, partial ASD closure, PDA divided	Failed to wean off bypass thus proceeded to ECMO. Transferred to ICU with open chest off inotropes. Developed DIC with persistent lactic acidosis, limbs ischaemic and mottled. Decannulated with immediate loss of cardiac output. Cultured ESBL Klebsiella on urine and tracheal aspirate.
4	Term Male 3170g	Hypoplastic LV, Aortic Stenosis (Unicuspid Aortic Valve), ASD		PDA ligation, Aortic arch reconstruction	Postop echo showed good repair and good cardiac function. Day two hypotensive, with raised septic markers, started nosocomial

				and aortic valvotomy	cover, fluid overloaded thus dialysis started. Extensive resus day 4 postoperatively – patient demised.
5	Term Male 3100g	DORV, TGA, PDA, VSD		Central shunt – aorta to RPA	Demised in ward day ten postop – patient file not found.
6	39/40 Male 3450g	Tetralogy of Fallot, severe RVOT obstruction, large VSD with bidirectional shunt, PDA, 50% aortic override of IVS, PA annulus 4mm, RPA 3-4mm LPA not seen		RVOT augmentation, PDA ligation	Good repair postop, flow in LPA not seen. Severe Pulmonary Hypertension, started on Nitric oxide, changed to HFOV. Echo – minimal flow in distal branch PAs – not amenable to further surgery. Serratia marcescens on tracheal aspirate. Forensic PM: possible hypoplastic left lung.
7	39/40 Male 3370g	Pulmonary atresia, Tricuspid atresia, ASD, PDA		Right modified Thomas- Blalock-	Remained Prostaglandin dependent – desaturation, loss of cardiac output whenever

				Taussig shunt – innominate to right Pulmonary artery	weaned. Demised in ward two days after ICU discharge.
8	39/40 Male 3500g	Extreme Tetralogy of Fallot, pulmonary atresia, ASD, VSD – flow from RV and LV to aorta and PDA. Hypoplastic MPA with some forward flow, small branch Pas	Dysmorphic – cleft lip and palate, abnormal feet, cryptorchidism, hypertelorism, large fontanelles, flat	LPA mobilized to hilum level. PDA ligated and divided. Pericardial patch for augmentation placed from	Two hours after admission sudden drop of saturation to twenties. Taken back to theatre – RVOT patch redone. No obvious obstruction or clot. Unable to come off bypass twice– severe desaturation. Readmitted to ICU and died next morning.

			nasal bridge, hypocalcaemia. Chromosomes normal, FISH for 22q11 negative	infundibulum across pulmonary valve (leaflets not resected) and down into LPA. LPA allowed 4mm hegar, MPA allowed 6mm	
9	39/40 Female 2900g	TGA with large VSD, ASD, PDA.	Microcephaly with absent corpus callosum on	PDA ligated, VSD closed, aorta and pulmonary	Severe postoperative hypotension unresponsive to triple inotropes and hydrocortisone. Echo showed extremely poor RV function and severely impaired LV function.

			<p>cranial ultrasound.</p> <p>Renal hypoplasia.</p> <p>Cleft lip and palate</p> <p>CRE screen positive for Klebsiella pneumonia</p> <p>Duplications on the 16p13.2 chromosomal region on DNA</p>	<p>artery switched with LeCompte maneuver. Re-implantation of coronary buttons challenging due to their eccentric location.</p>	<p>Chest opened – very poor myocardial contractility and heart mottled. Blood culture positive after 12 hrs – Serratia marcescens.</p>
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			microarray analysis		
10	37/40 Female 2690g	TGA type DORV, VSD		Surgery on day 11 of life challenging – difficulty in closing VSD as well as abnormal coronary anatomy	Severe hypotension postop requiring fluid boluses/adrenalin/noradrenaline/milrinone and steroids. Delayed chest closure on day 8. Prolonged ventilation with severe fluid overload, acute kidney injury, pleural effusions and ventilator associated pneumonia. Tracheostomy performed. Multiple confirmed episodes of sepsis – Acinetobacter, ESBL Klebsiella, Enterococcus... Demised on day 53 of ICU admission.
11	Term Female 3085g	Dextrocardia with functionally univentricular heart – Double inlet left ventricle with	Noted to have dysmorphic features	Central shunt – aorta to right	Initial ICU admission complicated by hypotension, hypoxia and supraventricular tachycardia. Extubated on day 8 post-surgery

		rudimentary right ventricle, single atrium, small pulmonary artery with subvalvar pulmonary stenosis and valvular pulmonary stenosis, MAPCAs	suggestive Turner syndrome – normal karyotype	pulmonary artery	and discharged from ICU. Reintubated day 9 for hypoxia, bilateral pleural effusions and chylothorax. Course complicated by wound dehiscence, nosocomial sepsis (multi drug resistant <i>Klebsiella pneumoniae</i> ). Died four days after ICU discharge.
12	Term Female 2760g	Truncus arteriosus, VSD		Truncus arteriosus repair	Epicardial echo – poor contractility, mild to moderate aortic regurgitation. Heart rested; adrenaline increased – no improvement. Heart dusky, coronary arteries patent. Procedure terminated, died on table.
13	34W Female 2600g	TGA, ASD, PDA		Arterial switch operation	Unsuccessful weaning off bypass – RV failure/right coronary button higher on the neo-aorta. RV function improved; function still significantly impaired. ECMO run for 2 days

					unremarkable. Remained inotrope and fluid bolus dependent. Forensic Post-mortem: RV infarction confirmed as haemorrhagic infarction on histology
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Table 2: Summaries of mortality at 30 day follow up

	Gestation in weeks/sex/weight	Echo and diagnosis	Associated conditions	Operation	Course in theatre/ICU and cause of death
1	Term Male 3650g	Coarctation of the aorta, PDA		End to end anastomosis, PDA ligation	Largely uneventful ICU stay. Discharged home after 11 days. Demised at district hospital 26 days postop – no details available
2	Term Male 3400g	Taussig Bing malformation (DORV, TGA, VSD), PDA		Arterial switch performed, no septostomy required	Postoperative hypotension. Seven days nitric oxide and High Frequency Oscillatory Ventilation. Acute kidney injury. Supraventricular tachycardia requiring Adenosine. Death on arrival at peripheral hospital two days post discharge – no further details available.
3	39/40 Male 3000g	Pulmonary atresia, VSD, PDA	22q11 microdeletion	RVOT reconstruction and	Discharged from ICU on second day postoperatively. Superficial sternal wound infection with dehiscence secondary to Methicillin sensitive Staphylococcus.

		supplying hypoplastic MPA		transannular MPA augmentation. VSD left for later repair	Discharged home ten days postoperatively. Readmitted to ICU with acute gastroenteritis and dehydration. Deteriorated with desaturation, vomiting and abdominal distension and later died. X-ray showed extensive pneumatosis.
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# APPENDICES

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## Demographic Information

Subject Code Number \_\_\_\_\_

*Auto populated by REDCap*

Patient ID Number \_\_\_\_\_

*(Please format as XXX\_YYYYYY, where "XXX" is your assigned site number and "YYYYYY" equals any numbering system your site would prefer to use. For example, a patient for site 005 might be entered as 005\_12345.)*

Date of birth: \_\_\_\_\_

Date of relevant surgery: \_\_\_\_\_

*(If a patient has more than one procedure during the same admission, use the information related to the procedure having the highest RACHS-1 Score.)*

Age at Surgery Category:

<=30 days     31 days to < 1 year     >=1 year and < 18 years     >=18 years

Age at Surgery Value \_\_\_\_\_

*(For example, if patient is 29 days old, enter 29. If patient is 11 months old, enter 11. If patient is 6 years old, enter 6.)*

Gender     female     male

Name of Site:    *Choose Red Cross from drop down menu*

## Pre-operative Status

Nutritional Appearance     Normal     Malnourished     Emaciated     Overweight

*Nutritional Appearance derived/calculated from .....*

Preoperative Procedures     not applicable     balloon atriostomy before surgery     resuscitation before surgery  
 ionotrope therapy before surgery     ventilation preoperatively

*Preoperative procedures found in Clerking Notes*

Is patient weight known?     Yes     No    Weight (kg) \_\_\_\_\_ (1 decimal place, e.g., 2.7)

Is patient height known?     Yes     No    Height (cm) \_\_\_\_\_ (1 decimal place, e.g., 27.3)


Patient hematocrit known?     Yes     No    Hematocrit (%) \_\_\_\_\_ (1 decimal place, e.g., 37.2)  
*Hematocrit results found in on-line NHLS*

Prematurity     Yes     No     Unknown  
*\*Based on gestational age; < 37 weeks*

Is patient oxygen saturation known?     Yes     No    O2 Saturation (%) \_\_\_\_\_

Other Pertinent Information: \_\_\_\_\_

*Height, weight, oxygen saturation and prematurity found in Anaesthesia Report (yellow sheet)*

*\*Prematurity also found in blue cover page. Look  for indicating TERM baby.*

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## Patient Diagnosis

### Cardiac Diagnosis

TIC ALL PATIENT DIAGNOSES THAT APPLY

Patient diagnoses are derived from Pink Echo Reports, Yellow ICU Discharge Summary Reports, and Blue Surgical/OR Notes

- AOLCA
- Aortic insufficiency
- Aorticopulmonary window
- Aortic stenosis, subvalvar
- Aortic stenosis, supra-valvar
- Aortic stenosis, valvar
- Aortic valve atresia
- ASD, common atrium (single atrium) ASD, coronary sinus
- ASD, NOS
- ASD, secundum ASD, sinus venosus
- AVC (AVSD), complete CAVSD
- AVC (AVSD), intermediate (transitional)
- AVC (AVSD), partial (incomplete) (PAVSD) (ASD, primum) Bicuspid Ao valve
- Coarctation of aorta
- Coarctation of the aorta and hypoplastic arch (neonatal type)
- Coarctation of the aorta and interrupted arch
- Conduit failure Congenitally corrected TGA
- Cor triatriatum
- Coronary to RA fistula
- DCRV
- DORV, IVS
- DORV, remote VSD (uncommitted VSD)
- DORV, TGA type
- DORV, TOF type DORV, VSD type
- Ebstein's anomaly
- Hypoplastic left heart syndrome (HLHS)
- Interrupted aortic arch
- MAPCA(s) (major aortopulmonary collateral[s]) (without PA-VSD)
- Mitral regurgitation
- Mitral stenosis, subvalvar
- Mitral stenosis, subvalvar, parachute
- Mitral stenosis, supra-valvar mitral ring
- Mitral stenosis, valvar
- Partial anomalous pulmonary venous connection (PAPVC)
- Patent ductus arteriosus
- PFO (with ASD)
- Peripheral PA branch stenosis
- Prosthetic valve failure
- Pulmonary artery stenosis, branch, central (within the hilar bifurcation)
- Pulmonary artery stenosis, branch, peripheral (at or beyond the hilar bifurcation)
- Pulmonary artery stenosis, NOS
- Pulmonary artery, discontinuous
- Pulmonary atresia, IVS
- Pulmonary atresia, IVS + coronary artery anomalies
- Pulmonary atresia, VSD (including TOF, PA)
- Pulmonary atresia, VSD-MAPCA (pseudotruncus)
- Pulmonary insufficiency
- Pulmonary stenosis, NOS Pulmonary stenosis, subvalvar
- Pulmonary stenosis, valvar
- Pulmonary vascular obstructive disease (Eisenmenger's)
- Pulmonary venous stenosis
- Rheumatic heart disease
- Shone's complex
- Single ventricle, double inlet
- Single ventricle, DILV
- Single ventricle, DIRV
- Single ventricle, heterotaxia syndrome

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**TIC ALL PATIENT DIAGNOSES THAT APPLY**

Patient diagnoses are derived from Pink Echo Reports, Yellow ICU Discharge Summary Reports, and Blue Surgical/OR Notes

- Single ventricle, HLHS type
- Single ventricle, mitral atresia
- Single ventricle, NOS
- Single ventricle, other
- Single ventricle, tricuspidatresia
- Single ventricle, unbalanced AV canal s/p PA band
- Is/p systemic-to-PA shunt
- Is/p Glenn/hemi-Fontan surgery
- ITGA, IVS
- ITGA, IVS-LVOTO
- ITGA, VSD
- ITGA, VSD-LVOTO
- Corrected transposition of GA TI
- ITOF, absent pulmonary valve
- ITOF, AVC (AVSD)
- ITOF, PA atresia
- ITOF, PA stenosis/hypoplasia
- TOF, absent AV canal
- TOF, absent pulmonary atresia
- Total anomalous pulmonary venous connection (TAPVC)
- Total anomalous pulmonary venous connection (TAPVC), NOS
- Total anomalous pulmonary venous connection (TAPVC), Type 1 (supracardiac)  Total anomalous pulmonary venous connection (TAPVC), Type 2 (cardiac)
- Total anomalous pulmonary venous connection (TAPVC), Type 3 (infracardiac)  Total anomalous pulmonary venous connection (TAPVC), Type 4 (mixed)
- Truncus arteriosus, type I, II, III, IV
- Vascular ring VSD, NOS
- VSD, Type 1 (subarterial) (supracristal) (conal septal defect) (infundibular)
- VSD, Type 2 (perimembranous) (paramembranous) (conovertricular)
- VSD, Type 3 (inlet) (AV canal type)
- VSD, Type 4 (muscular)
- VSD, Type: Gerbode type (LV-RA communication)
- VSD, multiple
- Other

If other, please specify: \_\_\_\_\_

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**NON-CARDIAC**

*For all non-cardiac information fields, check the Ward Clerking Notes as well as ICU Discharge Summary Report (Yellow Sheet)  
See IQIC Reference Guide page 11 for detailed instructions on recording Major non-cardiac structural anomaly*

Major non-cardiac structural anomaly?  Yes  No  
If yes, describe

Major chromosomal abnormality or syndrome?  Yes  No  Unknown  
If yes, describe

Major medical illness?  Yes  No  
If yes, describe

## Surgical Procedure

List all procedures in free text in order as they are listed on the Blue OR Reports separated by commas

Describe Surgical Procedure

Month of Surgery \_\_\_\_\_

Year of Surgery \_\_\_\_\_

Surgeon Name (and Other Assisting Personnel) \_\_\_\_\_

Performed in the presence of visiting cardiac surgical groups?  Yes  No

Number of operations or reoperations prior to surgery \_\_\_\_\_

*Does this question pertain to this admission or the patient's entire medical history?*

Open chest after surgery?  Yes  No

Required additional surgery for bleeding?  Yes  No If yes, describe \_\_\_\_\_

### RACHS-1 Risk Adjustment

Determine RACHS score using instructions in IQIC Reference Guide pages 12-13

*If more than one procedure in a single admission, use the most severe RACHS score. Refer to first page of this CRF to see relevant procedure date.*

Can RACHS-1 risk category be assigned?  Yes  No

Procedure Performed

- Atrial septal defect surgery (including atrial septal defect secundum, sinus venosus septal defect, patent foramen ovale closure)
- Aortopexy
- Patent ductus arteriosus surgery at age >30 days
- Coarctation repair at age >30 days
- Partially anomalous pulmonary venous connection surgery
- Aortic valvotomy or valvuloplasty at age >30 days
- Subaortic stenosis resection
- Pulmonary valvotomy or valvuloplasty
- Pulmonary valve replacement
- Right ventricular infundibulectomy
- Pulmonary outflow tract augmentation
- Repair of coronary artery fistula
- Atrial septal defect and ventricular septal defect
- Atrial septal defect primum repair
- Ventricular septal defect repair
- Ventricular septal defect closure and pulmonary valvotomy or infundibular resection
- Ventricular septal defect closure and pulmonary artery band removal
- Repair of unspecified septal defect
- Total repair of tetralogy of Fallot
- Repair of total anomalous pulmonary veins at age >30 days
- Glenn shunt
- Vascular ring surgery
- Repair of aorto-pulmonary window
- Coarctation repair at age less than or equal to 30 days
- Repair of pulmonary artery stenosis
- Transection of pulmonary artery
- Common atrium closure
- Left ventricular to right atrial shunt repair
- Aortic valve replacement
- Ross procedure
- Left ventricular outflow tract patch
- Ventriculomyotomy
- Aortoplasty

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- Mitral valvotomy or valvuloplasty
- Mitral valve replacement
- Valvectomy of tricuspid valve
- Tricuspid valvotomy or valvuloplasty
- Tricuspid valve replacement
- Tricuspid valve repositioning for Ebstein anomaly at age >30 days
- Repair of anomalous coronary artery without intrapulmonary tunnel
- Repair of anomalous coronary artery with intrapulmonary tunnel (Takeuchi)
- Closure of semilunar valve, aortic or pulmonary
- Right ventricular to pulmonary artery conduit
- Left ventricular to pulmonary artery conduit
- Repair of double outlet right ventricle with or without repair of right ventricular obstruction
- Fontan procedure
- Repair of transitional or complete atrioventricular canal with or without valve replacement
- Pulmonary artery band
- Repair of tetralogy of Fallot with pulmonary atresia
- Repair of cor triatriatum
- Systemic to pulmonary artery shunt
- Atrial switch operation
- Arterial switch operation
- Reimplantation of anomalous pulmonary artery
- Annuloplasty
- Repair of Coarctation and ventricular septal defect closure
- Excision of intracardiac tumor
- Aortic valvotomy or valvuloplasty at age less than or equal to 30 days
- Konno procedure
- Repair of complex anomaly (single ventricle) by ventricular septal defect enlargement
- Repair of total anomalous pulmonary veins at age less than or equal to 30 days
- Atrial septectomy
- Repair of transposition, ventricular septal defect, and subpulmonary stenosis (Rastelli)
- Atrial switch operation with ventricular septal defect closure
- Atrial switch operation with repair of subpulmonary stenosis
- Arterial switch operation with pulmonary artery band removal
- Arterial switch operation with ventricular septal defect closure
- Arterial switch operation with repair of subpulmonary stenosis
- Repair of truncus arteriosus
- Repair of hypoplastic or interrupted arch without ventricular septal defect closure
- Repair of hypoplastic or interrupted aortic arch with ventricular septal defect closure
- Transverse arch graft
- Unifocalization for tetralogy of Fallot and pulmonary atresia
- Double switch
- Tricuspid valve repositioning for neonatal Ebstein anomaly at age 30 days
- Repair of truncus arteriosus and interrupted arch
- Stage 1 repair of hypoplastic left heart syndrome (Norwood operation)
- Stage 1 repair of nonhypoplastic left heart syndrome conditions
- Damus-Kaye-Stansel procedure

RACHS-1 Category

- 1  2  3  4  5  6

Other pertinent medical information \_\_\_\_\_

## Outcome/Complications

In hospital death?  Yes  No

If yes, month of death \_\_\_\_\_

If yes, year of death \_\_\_\_\_

If yes, describe \_\_\_\_\_

Number of days from procedure to discharge \_\_\_\_\_

ICU Stay (hours) \_\_\_\_\_  
(For example, if length of ICU stay was 3 days, 30 minutes, enter 72 here.)

ICU Stay (minutes) \_\_\_\_\_  
For example, if length of ICU stay was 3 days, 30 minutes, enter 30 here.)

Ventilation time (hours) \_\_\_\_\_  
(For example, if length of ventilation time was 3 days, 30 minutes, enter 72 here.)

Ventilation time (minutes) \_\_\_\_\_  
(For example, if length of ventilation time was 3 days, 30 minutes, enter 30 here.)

Cardiopulmonary bypass (CPB) events? (formerly "perfusion events")  Yes  No

(Any significant CPB-related event that threatened the patient's safety)

If yes, describe \_\_\_\_\_

Surgical site infection?  Yes  No

If yes, specify  superficial incisional surgical site infection  
 DIP/DIS - deep incisional surgical site infection  
 mediastinitis

If yes, describe \_\_\_\_\_

Bacterial sepsis?  Yes  No

If yes, describe \_\_\_\_\_

Organism identified (if known) \_\_\_\_\_

Other major complications \_\_\_\_\_

## 30 Day Follow-up

Is patient alive?  Yes  No  Unknown

If no, number of days from procedure to death" \_\_\_\_\_

If yes, was patient contacted?  Yes  No

If yes, how was patient contacted?  Phone  Email  In person  Other If other, specify \_\_\_\_\_

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If yes, is patient alive and well?  Yes  No

Describe patient's current condition \_\_\_\_\_

## ***World Journal for Pediatric and Congenital Heart Surgery***

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Carl L. Backer, MD, Editor; Cincinnati Children's Hospital, Cincinnati, USA and University of Kentucky, Lexington, USA

Virginia F. Hawkins, Managing Editor

E-mail: [WJPCHS@gmail.com](mailto:WJPCHS@gmail.com)

Telephone: 302-326-9313

Website: <http://wjpchs.sagepub.com>

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#### **General Information**

*World Journal for Pediatric and Congenital Heart Surgery (WJPCHS)* is a bi-monthly, peer reviewed, scientific publication dedicated to the advancement and dissemination of knowledge pertaining to congenital cardiac anomalies, pediatric heart diseases in general, and surgical management in particular.

*WJPCHS* is the official journal of the [World Society for Pediatric and Congenital Heart Surgery \(WSPCHS\)](#), the [Congenital Heart Surgeons' Society \(CHSS\)](#), and the [European Congenital Heart Surgeons Association \(ECHSA\)](#).

*WJPCHS* publishes original reports of clinical and/or basic scientific investigations and observations relevant to the surgical and medical care and management of patients with congenital heart disease, as well as case reports, "how to do it" articles, image reports, new technology evaluations, review articles, historical reviews, book reviews, invited editorials, correspondence, and commentary. Consistent with the mission of the journal's founding organization, WSPCHS, the *World Journal for Pediatric and Congenital Heart Surgery* serves as a forum for individuals and organizations interested in providing "the highest quality comprehensive cardiac care to all patients with pediatric and/or congenital heart disease, from the fetus to the adult, regardless of the patient's economic means, with an emphasis on excellence in education, research, and community service."

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Transplantation for Congenital Heart Disease: Focus on the Impact of Functionally

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Univentricular Versus Biventricular Circulation. *World Journal for Pediatric and Congenital Heart Surgery*. 2021;12(3):352-359.

(List *all* authors if 6 or fewer; otherwise, list first 3 authors followed by “et al.”)

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#### **Chapter in Book**

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file should include a brief description of the supplementary data content, including supplemental figure legends.

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Revised manuscripts must be submitted in two parts as word-processing files: (1) revised, marked manuscript showing additions and deletions, preferably using Track Changes strike-through format for deletions and color font for additions; (2) revised, unmarked manuscript. A point-by-point response to reviewers' comments must be included in the appropriate field on the submission form.

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**UNIVERSITY OF CAPE TOWN**  
**Faculty of Health Sciences**  
**Human Research Ethics Committee**



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Grootes Schuur Hospital  
Observatory 7925

Email: [hrec-enquiries@uct.ac.za](mailto:hrec-enquiries@uct.ac.za)  
Website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms)

06 December 2019

**HREC REF: 872/2019**

**Prof L. Zühlke**  
Division of Paediatric Cardiology  
Department of Paediatrics and Child Health  
Red Cross War Memorial Children's Hospital

Dear Prof Zühlke

**PROJECT TITLE: OUTCOMES FOLLOWING NEONATAL CARDIAC SURGERY IN A TERTIARY CENTRE. (SUB-STUDY - R01/2014) (MASTER DEGREE - DR DERRIK DU TOIT)**

Thank you for submitting your new study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

**Approval is granted for one year until the 30 January 2021.**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period. (Forms can be found on our website: [www.health.uct.ac.za/fhs/research/humanethics/forms](http://www.health.uct.ac.za/fhs/research/humanethics/forms))

**The HREC acknowledges that the student: Dr D. Du Toit will also be involved in this study.**

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

**Please quote the HREC REF in all your correspondence**

Yours sincerely

**PROFESSOR MARC BLOCKMAN**  
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**

Federal Wide Assurance Number: FWA00001637.  
Institutional Review Board (IRB) number: IRB00001938  
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for

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