Cardiology in the Young

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Determining associations between prenatal maternal mental health and social determinants of health with outcomes in children with critical CHD

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Original Article

Cite this article: Lisanti AJ, Min J, Hampton L, Cole J, Budney A, Burnham A, Zimmerman L, Quarshie W, Shillingford AJ, and Gaynor JW (2025) Determining associations between prenatal maternal mental health and social determinants of health with outcomes in children with critical CHD. *Cardiology in the Young* **35**: 1654–1662. doi: 10.1017/S1047951125100772

Received: 11 March 2025
Revised: 11 March 2025
Accepted: 4 June 2025
First published online: 11 August 2025

Keywords:
Congenital heart disease; neurodevelopment; mental health; social determinants of health

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Abstract

Prenatal maternal mental health and social determinants of health may influence pregnancy, child hospitalisation, and child neurodevelopmental outcomes in critical congential heart disease (CHD). We examined 189 mother–child dyads of children born with CHD who underwent neonatal cardiac surgery and completed neurodevelopmental assessment between the ages 13 and 29 months. We used latent profile analysis to identify distinct maternal groups based on prenatal maternal mental health screening scores and individual- and neighbourhood-level social determinants of health factors. We examined the association between maternal groups with their child's gestational age, birth weight, hospital length of stay (HLOS), and neurodevelopment. Latent profile analysis identified two distinct groups: high-risk ($n = 46$) and low-risk ($n = 143$). Mothers in the high-risk group had higher mental health screening scores, lower age, higher social vulnerability, lower education, and were more likely to have Medicaid insurance and represent a minority group than mothers in the low-risk group. The high-risk group had children with lower gestational age and weight at birth, longer HLOS, and lower cognitive, language, and motor scales than children in the low-risk group ($p < 0.05$). Sensitivity analysis in mother–infant dyads without foetal extracardiac conditions found that significant relationships persisted in the high-risk group, with lower gestational age and lower language scale scores than the low-risk group ($p < 0.05$). Children of mothers with adverse prenatal maternal mental health and social determinants of health risks had significantly worse pregnancy and child outcomes. Interventions are critically needed to address maternal mental health and social determinants of health risks beginning in the prenatal period.

Introduction

Children born with critical congenital heart disease (CHD) are at increased risk for neurodevelopmental impairments that influence educational, occupational, and quality of life outcomes.[1,2] With decreasing CHD mortality related to advances in care, attention has shifted towards identifying modifiable risk factors that may optimise neurodevelopmental outcomes for this growing population.[3] While numerous clinical risk factors for neurodevelopmental impairment have been identified, most are medically necessary components of care and not easily modified.[4,5] Family-centred care, recognised as a core value and approach to care in paediatrics,[6–8] acknowledges the importance of providing care and support not only to the paediatric patient, but also to the child's parents and caregivers. Furthermore, family-centred care includes both health care and social care of paediatric patients and their families.[9–12]

Within this context of family-centred care, maternal mental health[13–16] and social determinants of health[17] are potential modifiable factors influencing child neurodevelopment in CHD that have yet to be studied in combination using longitudinal datasets. Undergoing a foetal echocardiogram and receiving a prenatal diagnosis of CHD is a significant stressor that impacts maternal mental health,[18] resulting in the development of enduring maternal mental health

symptoms.[13] While increased stress is expected in this context, prenatal stress can contribute to the development of maternal mental health pathologies such as major depressive disorder and post-traumatic stress disorder.[16,19,20] Maternal mental health risks of depressive and stress symptoms have also been shown to be associated with increased risk for worse pregnancy outcomes such as preterm birth and low birth weight infants.[21,22] Mothers experiencing additional social determinants of health adversities may be at greater risk and these risks may ultimately negatively influence child hospitalisation and neurodevelopmental outcomes in children with CHD.[13]

Social determinants of health contribute to population health outcomes, including mortality and quality of life.[23] Social determinants of health disparities have been shown to adversely influence neurodevelopmental outcomes and to be associated with higher mortality and worse quality of life.[24–35] These disparities have been demonstrated by social determinants of health factors, including maternal age and education,[27] insurance type,[34] community-level socioeconomic risk,[33] and race and ethnicity.[27,35] However, the extent to which these disparities, combined with prenatal maternal mental health symptoms, affect children with CHD is unknown. Using clustering methods of social determinants of health and mental health variables may provide new insights into the differing levels vulnerability of these paediatric patients and their mothers.[36]

We utilised the Parental Stress and Resilience in CHD Model to study the association between maternal mental health symptoms and social determinants of health risks on outcomes in children with CHD. The Parental Stress and Resilience in CHD Model (Figure 1) was specifically developed to provide a framework of parental stress in CHD through a health equity lens and identifies parent demographic, mental health, and social determinants of health variables influencing parental and child outcomes, including parent sex, race and ethnicity, socioeconomic status, and neighbourhood environment.[13] These relationships have been posited for the general population, as a recent review of literature highlighted the critical need for interventions targeting social determinants of health and psychosocial conditions in early pregnancy.[37] This study explored the combined influence of prenatal maternal mental health symptoms and maternal social determinants of health risks on pregnancy outcomes and hospitalisation and neurodevelopmental outcomes in children with CHD.

Materials and methods

This retrospective cohort study examined 189 mother–child dyads of children born with CHD who underwent neonatal cardiac surgery, linking child electronic health record data with their mothers' prenatal demographics and maternal mental health screening. Inclusion criteria for our sample were all children with CHD who had neonatal cardiac surgery, who completed neurodevelopmental assessment at 13 to 29 months of age between 1 December, 2012, and 30 November, 2019, and whose mothers completed prenatal mental health screening for depression and post-traumatic stress at one of their early prenatal visits to our centre for foetal diagnosis and treatment. This window of time reflects the time period after we began a prenatal mental health screening programme at our institution as a part of standard clinical practice[38,39] and before the start of the COVID-19 pandemic, which may confound variables in our study, including maternal mental health and child neurodevelopment. Children who underwent cardiac surgery for CHD >30 days of age were excluded, as well as those children with mothers who did not have prenatal maternal mental health screening.

Study data were collected and managed using Arcus resources hosted at Children's Hospital in Philadelphia. Arcus is a suite of tools and services developed to enhance research efforts at Children's Hospital in Philadelphia by helping researchers to explore available data, see overlaps among datasets, build new cohorts, and determine if there are data or samples available for additional research projects. Incubated within the Department of Biomedical and Health Informatics, Arcus connects the hospital's clinical and research data to enable biomedical researchers to conduct highly innovative, data-driven, reproducible research within a managed, scalable framework. This framework includes 1) user access controls; 2) patient privacy and confidentiality protections through regulatory review; 3) electronic honest-brokered data de-identification and re-identification; and 4) data retention, management, sharing, and destruction services in an auditable computational environment.

Measures

Child demographic and clinical data

Data were abstracted from our electronic health record and local registries on the following demographic and clinical variables: sex, extracardiac conditions (i.e. chromosomal anomaly, extracardiac anomaly, syndrome), pre-operational complications (i.e. preoperative cardiac arrest, extracorporeal membrane oxygenation, mechanical ventilation, seizures, or inotropes), STAT category (i.e. Society of Thoracic Surgeons and European Association for Cardiothoracic Surgery Congenital Heart Surgery Mortality Score),[40] and cardiopulmonary bypass times (i.e. total minutes for the first STAT category operation in the hospitalisation).

Prenatal maternal mental health symptoms

Prenatal maternal mental health screening provided data on depressive and post-traumatic stress symptoms of mothers of children diagnosed with CHD using the *Postpartum Depression Screening Scale* and the *Impact of Events Scale—Revised.* The *Postpartum Depression Screening Scale is* a 35-item self-report instrument that assesses for depressive risk in postpartum women.[41] The *Postpartum Depression Screening Scale* is a reliable and valid measure that has been used with women across the perinatal period.[41,42] Scores of at least 60 signify significant depressive symptoms, and scores of at least 80 screen positive for likely postpartum depression. The *Impact of Events Scale—Revised* is a 22-item self-report instrument that assesses subjective distress caused by traumatic events.[43] Pregnant mothers were asked to identify a specific stressful life event (in this case, at the time of the foetal CHD diagnosis) and then indicate their level of distress for each "difficulty" listed during the past seven days. The *Impact of Events Scale—Revised* yields a total score (ranging from 0 to 88), and subscale scores can also be calculated for the Intrusion, Avoidance, and Hyperarousal subscales.[44] Scores of at least 23 signify significant post-traumatic stress symptoms and of at least 33 screen positive for likely post-traumatic stress disorder. Although both instruments have cut-off scores for screening, we used continuous *Postpartum Depression Screening Scale* and

https://doi.org/10.1017/S1047951125100772 Published online by Cambridge University Press

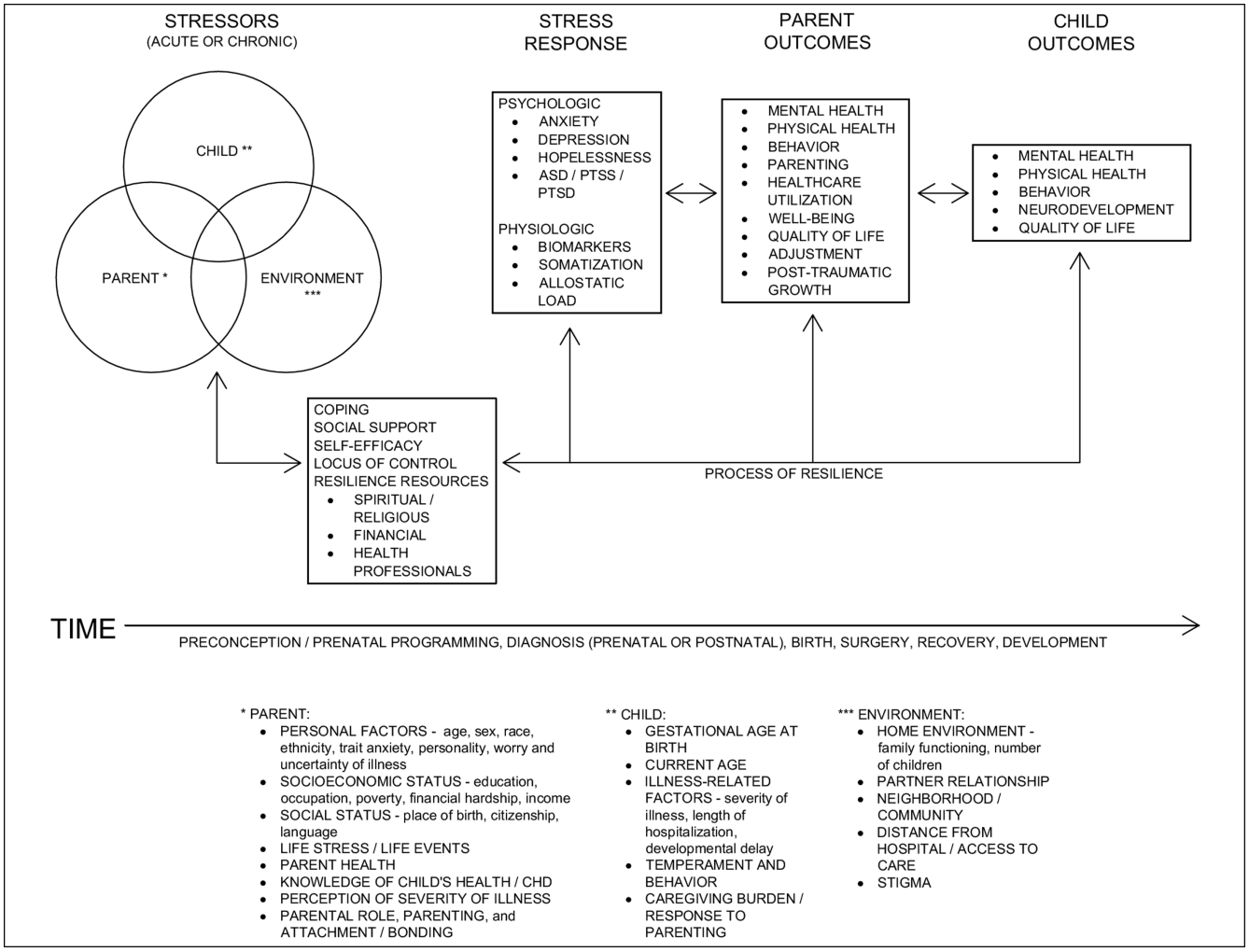


Figure 1. The parental stress and resilience in CHD model.

Impact of Events Scale—Revised scores to capture the extent of depressive and post-traumatic stress symptoms, since categories with low frequencies are difficult to fit into a latent model due to limited distributional information.

Maternal prenatal social determinants of health

Due to the lack of standardised data elements measuring social determinants of health in the electronic health record,[45] we incorporated individual-level social determinants of health and neighbourhood-level social determinants of health variables that were available in the electronic health record to provide a more comprehensive social determinants of health risk profile.[46]

Individual-level social determinants of health variables

Demographic data from the child's mothers were pulled from our local data registry of prenatally diagnosed mothers cared for in our foetal care centre. We pulled data available from the mothers' first prenatal visit, including maternal age, race and ethnicity, insurance type, education level, and home address.

Neighbourhood-level social determinants of health variable

We geocoded patients' home addresses at the time of ICU admission and defined their residential census tracts to represent their neighbourhood-level socioeconomic risk. We identified the neighbourhood socioeconomic characteristics using the US Centre for Disease Control and Prevention's 2014, 2016, and 2018 social vulnerability index.[47] The social vulnerability index was matched with the year of the mother's prenatal visit: 2014–2015 visits with social vulnerability index 2014, 2016–2017 visits with social vulnerability index 2016 and 2018 visits with social vulnerability index 2018. The social vulnerability index is a ranking system that evaluates a community's resilience following public health disasters across all US census tracts as percentiles. It is based on 15 social factors in four domains, including socioeconomic status, household composition-disability, minority status-language, and housing type-transportation. A higher score indicates that a community is more vulnerable. We classified the overall social vulnerability index score as low (< 25th percentile), moderate (25–49th percentile), substantial (50–74th percentile), and high (≥ 75th percentile).

https://doi.org/10.1017/S1047951125100772 Published online by Cambridge University Press

Pregnancy outcomes

Child gestational age and weight at birth were abstracted from our electronic health record to examine as pregnancy outcomes.

Child hospitalisation outcome

Hospital length of stay (HLOS) was calculated in days using the hospital admission and hospital discharge dates abstracted from our electronic health record.

Child neurodevelopment outcome

Neurodevelopment was assessed using the Bayley Scales of Infant and Toddler Development, 3rd Edition.[48] This is a standardised measure that evaluates cognitive, language, and motor skills through age-appropriate materials and is administered by a trained developmental practitioner. Items are administered until a basal and ceiling are obtained, and standard scores are calculated for each domain based on age-grouped normative samples. Neurodevelopmental assessment of children in our sample was completed in the recommended window between 13 and 29 months of age.[49]

Analysis

We described mother and infant characteristics using descriptive statistics. We examined possible selection bias by comparing infant characteristics between our study sample and the entire infant cohort using Chi-squared test, *t*-test, and Mann–Whitney *U* test. To identify maternal classes, first, we selected maternal demographic and social determinants of health characteristics as age, race and ethnicity, insurance type, education, and the social vulnerability index overall score based on their significant associations with any infant outcomes (i.e. gestational age at birth, birth weight, HLOS, neurodevelopment) in bivariate regression analysis ($p < 0.05$). Using latent profile analysis, including the above five characteristics and *Postpartum Depression Screening Scale* and *Impact of Events Scale—Revised* scores, we identified the two distinct maternal classes. Latent profile analysis is a probabilistic modelling algorithm that allows clustering of data and statistical inference. Once the clusters are mathematically identified, the classes are homogeneous within but distinct from each other. Regarding the optimal number of classes, we consider both model fit indices and clinical interpretability. The separation of the classes should be meaningful from a clinical standpoint.[50] As model complexity increases, the number of observations in each class inevitably gets smaller, potentially decreasing the generalizability of clustering. We selected two classes (Bayesian Information Criterion = 6964.15) since the three classes (Bayesian Information Criterion = 6875.64) ended up with low generalizability (less than 10% in the smallest group; $n = 17$, 72, and 136).[50] We conducted a sensitivity analysis with three maternal classes. We also duplicated the latent profile analysis with depressive and post-traumatic stress cut-off scores instead of continuous *Postpartum Depression Screening Scale* and *Impact of Events Scale—Revised* scores, and these models yielded trivial differences in effect estimates.

To examine the association between maternal classes and pregnancy, hospitalisation, and neurodevelopmental outcomes, we used continuous scores for all outcome measures. We used regression models after adjusting for infant sex as a biological variable for all outcomes. Due to the small sample size, we refrained from adjusting for several covariates. For the hospitalisation and neurodevelopmental outcomes, we chose two covariates in addition to infant sex that provided context on the infant's pre- and post-operative trajectory: pre-operational complications and STAT category. We did not adjust for cardiopulmonary bypass time due to its collinearity with STAT categories ($p < 0.001$). STAT category and HLOS (<14 days, 14–29 days, and ≥30 days) showed a dose-response relationship (e.g. proportions of HLOS <14d across STAT categories 1 through 5: 43, 59, 21, 18%, and 7%, $p < 0.001$). Finally, we did not include extracardiac conditions (chromosomal anomaly, extracardiac anomaly, syndrome) in the model because the high-risk mothers were more likely to have extracardiac conditions than the low-risk mothers (59 vs. 39%, $p = 0.02$). Given the temporal relationship of prenatally diagnosed fetal complications and maternal mental health, maternal classes inherently capture the impact of previously observed foetal extracardiac conditions. Therefore, adjusting for foetal extracardiac conditions in the model could result in over-adjustment when analysing neurodevelopmental outcomes. However, we did perform a sensitivity analysis in the subset of mother-infant dyads without foetal extracardiac conditions to determine whether observed relationships remained significant in that subgroup ($n = 133$).

Results

Among 189 mothers, the majority were non-Hispanic White ($n = 135$, 71%), and 79% of them were privately insured (Table 1). The mean gestational age at the maternal mental health screening was 29.3 weeks. Mean scores on the *Postpartum Depression Screening Scale* were 63.3 (Standard Deviation, SD = 21.7) and for the *Impact of Events Scale—Revised* were 18.1 (SD = 16.4). Mothers represented a full range of social vulnerability index categories, with approximately one-third of mothers in the substantial or high social vulnerability categories, one-third in the moderate social vulnerability category, and one-third in the low social vulnerability category. Infants in our cohort underwent surgeries representing a full range of STAT categories,[40] 44% had extracardiac conditions related to chromosome anomalies, extracardiac anomalies, or syndromes, and 31% had pre-operational complications, such as preoperative ventilation, stroke, inotropes, and sepsis (Table 1). There was no selection bias in infant demographics and clinical characteristics when comparing our sample ($n = 189$) to the entire infant cohort ($n = 647$).

A latent profile analysis identified two distinct groups that differed in maternal mental health measures and demographics: a high-risk group ($n = 46$) and a low-risk group ($n = 143$; Figure 2). Mothers in the high-risk group had significantly higher *Impact of Events Scale—Revised* scores (mean (SE): 23.2 (2.7) vs. 16.3 (1.4)) and *Postpartum Depression Screening Scale* scores (mean (SE): 69.7 (3.6) vs. 61.1 (1.9)) than those in the low-risk group. They were also younger (24.5 (0.7) vs. 32.6 (0.4)), had a higher social vulnerability index (47.9 (4.4) vs. 37.7 (2.5)), lower education levels (less than college: 91% vs. 14%), and were more likely to receive Medicaid (63% vs. 6%) and belong to a racial/ethnic minority group (60% vs. 17%).

Infants born to high-risk mothers had a shorter gestational age (Beta (SE) = –0.45 (0.21) days) and lower weight (–0.21 (0.09) kg) at birth. They also had a longer HLOS (24.5 (6.9) days), and lower cognitive (–4.3 (2.1)), language (–8.6 (2.8)), and motor scale scores (–5.4 (2.5)) than infants in the low-risk group (all $p < 0.05$; Table 2). A sensitivity analysis, which compared three maternal classes, also showed consistent results, although some significant differences disappeared (Supplementary Table 1). We also

https://doi.org/10.1017/S1047951125100772 Published online by Cambridge University Press

Table 1. Maternal and infant characteristics

Maternal characteristics during the prenatal visit (n = 189)	n (%) or M (SD)
Gestational age at the maternal mental health screening	29.3 (3.7)
Age	30.4 (5.1)
Race	
Asian	7 (4%)
Black or African American	19 (10%)
Hispanic or Latino	16 (9%)
Other	12 (6%)
White	135 (71%)
Insurance type at first screening	
None	1 (1%)
Private	150 (79%)
Medicaid	38 (20%)
Highest education level completed	
Less than College	65 (34%)
College	83 (44%)
More than college	41 (22%)
Prenatal PDSS*	63.3 (21.7)
Prenatal IESR*	18.1 (16.4)
SVI* overall score	40.4 (28.5)
Low	70 (37%)
Moderate	56 (30%)
Substantial	30 (16%)
High	33 (17%)
Infant clinical and demographic characteristics (n = 189)	**n (%) or M (SD)**
Sex	
Female	69 (36%)
Male	120 (64%)
Race	
Asian	3 (1%)
Black or African American	17 (9%)
Indian	1 (1%)
Multi-racial	10 (5%)
Other	35 (19%)
White	123 (65%)
Ethnicity	
Hispanic Or Latino	25 (13%)
Not Hispanic Or Latino	164 (87%)
Gestational age at birth (weeks)	38.34 (1.24)
Extracardiac conditions	
Chromosomal anomaly	44 (23%)
Extracardiac anomaly	62 (33%)
Syndrome	36 (19%)
STAT category	
1	14 (7%)
2	46 (24%)
3	39 (21%)
4	22 (12%)
5	68 (36%)
CPB Times for the first operation*	81 (31)
Hospital Length of Stay (days)	31 (42)
Pre-operational complications:**	
Preop ventilation	45 (24%)
Preop stroke	15 (8%)
Preop inotropes	11 (6%)
Preop sepsis	8 (4%)
Bayley Scales of Infant Development:***	
Cognitive composite	92 (13)
Language composite	89 (17)
Motor composite	89 (15)

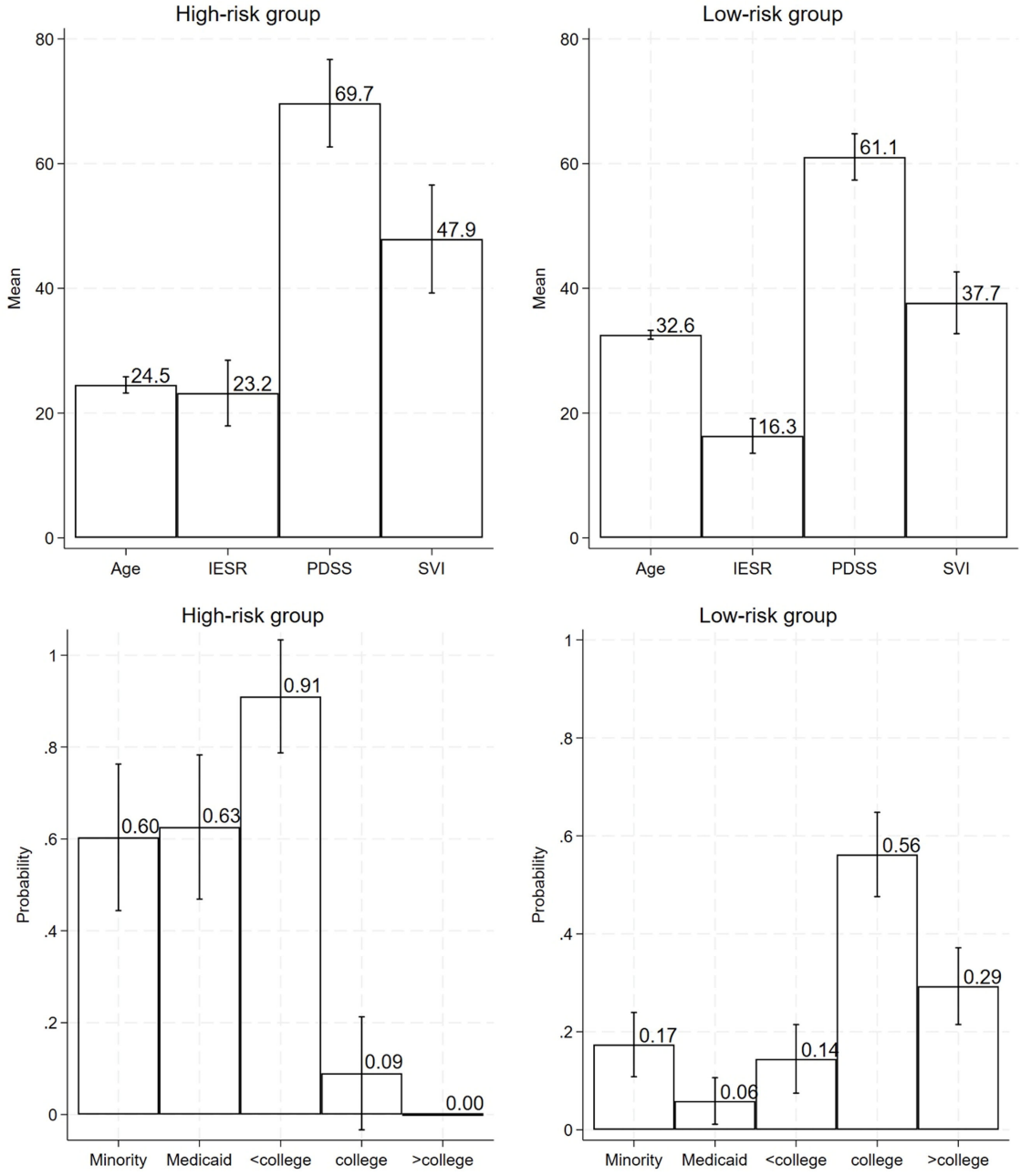
*PDSS = Postpartum Depression Screening Scale; IESR = Impact of Events Scale—Revised; SVI = Social Vulnerability Index; CPB = cardiopulmonary bypass.
** No one had pre-operational ECMO.
***Bayley measures had 3% missing in motor domain and 1% missing in language domain.

performed a sensitivity analysis in the subgroup of mother infant dyads without foetal extracardiac conditions and found that among this group of dyads (n = 133), infant born to high-risk mothers had a shorter gestational age (Beta (SE) = –0.62 (.27); p = 0.02) and lower language scale scores (Beta (SE) = –9.9 (3.4); p = 0.004).

Discussion

Despite decades of research describing neurodevelopmental outcomes of children born with CHD,[1] only recently have psychosocial factors such as maternal mental health and social determinants of health been recognised as important contributors.[2,51] Grounded in the Parental Stress and Resilience in CHD model, this exploratory latent profile analysis is the first to describe an at-risk group of mother–child dyads based on prenatal maternal mental health symptoms in combination with social determinants of health factors. We found worse outcomes in children with CHD born to pregnant mothers experiencing maternal mental health and social determinants of health adversities, including higher depressive and traumatic stress symptoms, lower age, higher social vulnerability index, lower education, and more likely to have Medicaid insurance and represent a minority group. These latent profiles of high- versus low-risk mother groups were differentially associated with worse pregnancy outcomes, including lower gestational age and birth weight, worse child hospitalisation outcome of longer HLOS, and worse child neurodevelopmental outcomes by lower cognitive, language, and motor scales. Significant findings persisted for gestational age and language

https://doi.org/10.1017/S1047951125100772 Published online by Cambridge University Press



Latent profile analysis using four continuous variables (maternal age, PDSS, IESR and SVI scores), two binary variables (race/ethnicity: non-Hispanic white vs. minority; insurance type: Medicaid vs. all others), and one categorical variable (maternal education level). The bars indicate 95% CI.

Figure 2. Two defined maternal classes by latent profile analysis. PDSS = postpartum depression screening scale; IESR = impact of events scalerevised; SVI = social vulnerability index.

scale scores in the sensitivity analysis of the subgroup without foetal extracardiac conditions, indicating that maternal mental health and social determinants of health risks have an influence on outcomes that should be explored in future research.

We acknowledge that multiple factors contribute to the presence of neurodevelopmental impairment in children with CHD, including prenatal abnormalities of the central nervous system (e.g. periventricular leucomalacia, smaller head circumference),[1,52] the complexity of CHD,[53] underlying genetic abnormalities,[54–58] low birth weight,[54,56,57] and longer hospital lengths of stay.[54,56,57,59–61] However, these factors have been shown to explain only one-third of the variance contributing to worse neurodevelopmental outcomes in CHD.[62–64] Thus, it is important to identify new, modifiable risk factors to optimise neurodevelopmental outcomes for the growing population of CHD survivors. The use of latent profile analysis provides a greater understanding of the combination of maternal mental health and social determinants of health risks that may influence pregnancy and child outcomes in CHD. More research is needed to understand whether any causal pathways or direct associations

https://doi.org/10.1017/S1047951125100772 Published online by Cambridge University Press

Table 2. Differences in child health outcomes between high-risk mothers (n = 46) and low-risk mothers (n = 143)

	Gestational age (weeks)	Birth weight (kg)	HLOS (days)	Cognitive score	Language score	Motor score
1. Unadjusted model						
Beta	−0.45	−0.20	25.85	−4.88	−9.16	−6.12
(SE)	(0.21)	(0.09)	(6.93)	(2.12)	(2.82)	(2.53)
p	0.0326	0.0298	0.0003	0.0224	0.0014	0.0166
2. Adjusted model						
Beta	−0.45	−0.21	24.53	−4.33	−8.63	−5.38
(SE)	(0.21)	(0.09)	(6.93)	(2.12)	(2.83)	(2.53)
p	0.0341	0.0215	0.0005	0.0426	0.0027	0.0348

Reference group in the regression model: Low-risk mothers. Adjusted models included for infant sex for all outcomes. For hospital length of stay (HLOS) and Bayley measures, we adjusted for pre-operational complications and STAT category additionally.

exist between the variables examined. Although there are likely complex interactions that can be studied further, of clinical importance is noting that at-risk mothers and their children with CHD need supportive intervention to mitigate maternal mental health and social determinants of health risks. Mothers of children born with CHD are known to be at risk for maternal mental health adversity and profound psychological distress.[16] Yet, routine mental health screening and social care screening are not the universal standard of care in paediatrics.[15,65,66] Mothers experiencing mental health or social determinants of health adversities need to be identified and supported during routine, family-centred, paediatric practice.

Future research with larger sample sizes may uncover the complexities of the relationships and underlying mechanisms influencing child clinical and neurodevelopmental outcomes. For example, prenatal maternal mental health and social determinants of health adversities may negatively influence the growth and development of the foetus in utero, thereby placing the child at greater risk for negative outcomes after birth. Maternal mental health and social determinants of health adversities experienced by mothers prenatally may have persisted postnatally, which can further impact both the mother and the child. The negative impact of untreated parental mental health problems on long-term child cognitive and behavioural development is well established.[67–69] Negative child outcomes may be the result of impaired parent–child interactions and changes in typical parenting behaviour.[70] Preliminary evidence suggests maternal mental health has greater influence on infant and child behavioural outcomes than the child's severity of illness in CHD.[71–73] Interestingly, a meta-analysis of early interventions involving parents of premature infants has demonstrated positive impacts on infant neurodevelopment.[74] Limited interventional studies have targeted maternal mental health in CHD;[15] however, none have targeted both maternal mental health and social determinants of health. Additional research is needed to demonstrate effective strategies to support outcomes in both mothers and their children born with CHD.

Limitations

We acknowledge the limitations of retrospective studies and that inherent biases may exist in the final analytic sample. Studies have found that patients with social determinants of health adversity have lower rates of CHD prenatal detection and higher incidence of loss to follow up.[26,75] Future studies with larger, prospective samples should explore whether the relationships found in this study are confirmed. We also acknowledge that there may be an intervention effect from the psychosocial services provided to pregnant mothers in our foetal care centre that we could not capture or measure. We did not have access to the mothers' electronic health record and were limited to maternal data available in the foetal care centre's data registry. Therefore, we could not include other clinical information on the mothers, such as pregnancy complications like hypertension or gestational diabetes, that may influence the outcomes we examined in this study. There may also be other maternal mental health symptoms that influence outcomes, including anxiety, stress, or other mental health diagnoses that were not covered in this study. We did not explore trajectories of maternal mental health symptoms and whether maternal mental health symptoms preceding the pregnancy or those developing during or in response to pregnancy or during child hospitalisation influenced outcomes. Future longitudinal studies are recommended that can provide a more complete examination of maternal mental health symptoms over time.

Conclusion

Our findings provide preliminary evidence for identifying potential disparities that can inform the design of interventions, improving the identification of at-risk mothers, and targeting individualised treatment approaches for maternal mental health symptoms and social determinants of health risks. Ongoing efforts to strengthen community and legislative engagement focused on supporting maternal mental health and reducing social determinants of health risk to address health care disparities may improve outcomes for children born with CHD and their families.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S1047951125100772.

Acknowledgements. None.

Financial support. This work was supported by the Cardiac Centre at Children's Hospital in Philadelphia. Study data were collected and managed using Arcus resources hosted at the Children's Hospital in Philadelphia.

Competing interests. The authors declare none.

Ethics standards. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant United States of America national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the Children's Hospital in Philadelphia's institutional review board.

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