Multicentre study protocol comparing standard NRP to developed Educational Modules for Resuscitation of Neonates in the Delivery Room with Congenital Heart Disease (LEARN-CHD)

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Abstract

Introduction Infants born with critical congenital heart defects (CCHDs) have unique transitional pathophysiology that often requires special resuscitation and management considerations in the delivery room (DR). While much is known about neonatal resuscitation of infants with CCHDs, current neonatal resuscitation guidelines such as the neonatal resuscitation programme (NRP) do not include algorithm modifications or education specific to CCHDs. The implementation of CCHD specific neonatal resuscitation education is further hampered by the large number of healthcare providers (HCPs) that need to be reached. Online learning modules (eLearning) may provide a solution but have not been designed or tested for this specific learning need. Our objective in this study is to design targeted eLearning modules for DR resuscitation of infants with specific CCHDs and compare HCP knowledge and team performance in simulated resuscitations among HCPs exposed to these modules compared with directed CCHD readings.

Methods and analysis In a prospective multicentre trial, HCP proficient in standard neonatal resuscitation programme education curriculum are randomised to either (a) directed CCHD readings or (b) CCHD eLearning modules developed by the study team. The efficacy of these modules will be evaluated using (a) individual preknowledge/postknowledge testing and (b) team-based resuscitation simulations.

Ethics and dissemination This study protocol is approved by nine participating sites: the Boston Children's Hospital Institutional Review Board (IRB-P00042003), University of Alberta Research Ethics Board (Pro00114424), the Children's Wisconsin IRB (1760009-1), Nationwide Children's Hospital IRB (STUDY00001518), Milwaukee Children's IRB (1760009-1) and University of Texas Southwestern IRB (STU-2021-0457) and is under review at following sites: University of Cincinnati, Children's Healthcare of Atlanta, Children's Hospital of Los Angeles and Children's Mercy-Kansas City. Study results will be disseminated to participating individuals in a lay format and presented to the scientific community at paediatric and critical care conferences and published in relevant peer-reviewed journals.

Strengths and limitations of this study

⇒ In a prospective multicentre trial, healthcare providers proficient in standard neonatal resuscitation programme education curriculum and randomised to directed critical congenital heart disease (CCHD) readings or CCHD eLearning modules developed by the study team.

⇒ A set of targeted eLearning modules aimed at delivery room (DR) resuscitation of infants with three specific CCHD lesions: (a) transposition of great arteries with intact ventricular septum with restricted atrial-level blood flow, (b) hypoplastic left heart syndrome and (c) congenital third-degree heart block will be designed and implemented at all sites.

⇒ The efficacy of these modules will be evaluated using (a) individual preknowledge/postknowledge testing and (b) team-based resuscitation simulations.

⇒ The pilot nature of this study and significance may limit the generalisability of the data, but provides proof of concept for future prospective analysis.

⇒ Since this trial tested only three cardiac lesions, further work is needed to develop eLearning modules for other critical congenital heart diseases that may result in cardiopulmonary compromise in the DR.

Introduction

Background Congenital heart defects (CHDs) are the most common type of congenital anomaly, many of which require resuscitation of affected infants in the immediate postnatal period.1 Even with early detection and prenatal diagnosis, some CHDs still carry high perinatal morbidity and mortality associated with their unique and complex transitional pathophysiology.2 Optimal delivery room (DR) resuscitation and stabilisation have become even more critical to long-term health and survival in the highest-risk CHDs, termed critical congenital
heart disease (CCHD) in patients that require surgery in the neonatal period or have congenital arrhythmias.\textsuperscript{3-7} Furthermore, close to 10% of neonates with CHD require resuscitation at time of birth, with the majority of them being those with CCHD.\textsuperscript{8}

The neonatal resuscitation programme (NRP) sponsored by the American Academy of Pediatrics (AAP) and the American Heart Association (AHA) provides an evidence-based algorithm for the resuscitation of neonates in the DR.\textsuperscript{9} NRP principles of ventilation-based stabilisation, oxygen saturation targets, heart rate assessments are based on newborns with normal cardiac structure and physiology and may not adequately address the unique needs of newborns with CHDs. For example, the focus on resuscitation of a newborn with a structurally normal heart focuses on the establishment of adequate ventilation prior to focusing on cardiovascular health.

For newborns with CCHDs and congenital arrhythmias, focusing initially on oxygen saturation goals may be insufficient to support haemodynamic stability in the immediate postnatal period. Specifically, age-based oxygen saturation targets derived from unaffected newborns may be unachievable and inappropriate for infants with cyanotic CHDs, potentially leading to excessive use of oxygen and ventilation. Studies have characterised this divergence from typical oxygen saturation norms and have suggested standardised DR management schema for newborns with CCHD.\textsuperscript{10,11} For infants with congenital arrhythmias such as complete heart block, heart rate may be an unreliable marker of haemodynamic stability. Finally, particular CCHD specific interventions (eg, initiation of prostaglandins to maintain ductal patency) may be needed. Initiation of prostaglandins in the DR for hypoplastic left heart syndrome (HLHS) and transposition of great arteries (TGA) has become standard of care.\textsuperscript{12}

It can be challenging to prepare for CCHD at risk for haemodynamic instability at birth. Several risk stratification models have been proposed based on the type of lesion, presence of additional conditions such as hydrops, and additional findings seen on fetal ultrasound.\textsuperscript{13,14} The AHA Statement on Fetal Cardiology summarised these models and ranked CCHD from lowest likelihood of instability to high probability of requiring special consideration in resuscitation.\textsuperscript{15} Lesions at increased risk for instability and often need specialised resources and personnel in the DR, included d-TGA with restrictive/intact foramen ovale, uncontrolled arrhythmia and HLHS with restricted foramen ovale.

Importance of development of education modules focused on CCHD in the DR

Recently, NRP has expanded to include ‘Special Considerations’ to guide the DR resuscitation of populations with unique needs, including extremely preterm infants, infants with airway anomalies and infants with maternal opioid exposures.\textsuperscript{9} However, NRP does not currently provide guidance for optimal DR resuscitation of neonates with CCHDs or congenital arrhythmias. Healthcare providers (HCPs) must therefore rely on personal experience, institutional protocols (if they exist) or literature reviews to guide their resuscitation of newborns with CCHDs or arrhythmias, leading to practice variability which could impact clinical outcomes. Given the large geographic area of Canada and the USA, some neonates with CCHD are born outside of tertiary centres in places with minimal experience of managing CCHD in the DR. Therefore, there is a need for educational materials on DR management of CCHDs and congenital arrhythmias to supplement standard NRP guidelines.

Emerging evidence suggests that to effectively incorporate these considerations into existing neonatal resuscitation practices, standardised, diagnosis-specific and multidisciplinary algorithms and education are required.\textsuperscript{11} Ideally, CHD specific supplemental education should be complementary to standard NRP, easily accessible, and geared towards HCPs in different settings.

There has also been a recent shift in resuscitation education from all in-person classrooms to the electronic platform, eLearning, combined with in-person practice skills.\textsuperscript{16,19} E-Learning uses diverse electronic modalities such as simulation, interactive reviews of clinical cases and self-paced learning to reach a greater audience.\textsuperscript{16,20} Although there has been an increase in using electronics for medical education, very few eLearning materials focus on the immediate management of CCHD.

**RESEARCH HYPOTHESIS AND STUDY OBJECTIVES**

To address the critical gap in immediate DR management of certain CCHD, we aim to create easily accessible, online eLearning modules on CCHD management to supplement current AAP-NRP and Canadian Pediatric Society NRP. We hypothesise that eLearning modules targeted towards neonatal DR resuscitation of infants with CCHD improves HCP technical performance compared with directed CCHD readings. Direct CCHD readings are common journal articles available and described below. By making eLearning education accessible to providers across North America, particularly those with limited exposure to deliveries of neonates with CCHD, these modules hold the potential to contribute to and enhance HCP providers’ resuscitation competency. As such, to assess the efficacy of these modules, we will perform a multi-centred randomised study comparing neonatal HCPs exposed to either directed CCHD readings or CCHD e-Learning developed by the study team (with fetal cardiology content experts), using pre-exposure and postexposure knowledge testing and postexposure team-based simulations as metrics.

The primary objective of this study is to design and implement a set of targeted eLearning modules aimed at DR resuscitation of infants with three specific CCHD lesions; (a) transposition of great arteries with intact ventricular septum (TGA-IVS) with restricted atrial level blood flow, (b) HLHS and (c) congenital third-degree heart block. The secondary objectives are to (a)
determine the acceptability of eLearning modules to supplement current education on neonatal resuscitation with the addition of eLearning modules on resuscitation of infants with CCHD, (b) compare CCHD specific DR resuscitation knowledge before and after completion of standard NRP resuscitation curriculum and either directed reading or specific CCHD eLearning and (c) contrast measures of technical and non-technical team performance in simulated resuscitation of infants with CCHD after the completion of CCHD eLearning with team performance after CCHD directed reading.

**METHODS AND ANALYSIS**

**Design, setting and study population**

This will be a two-phase, multi-centre prospective study that will be conducted from 1 January 2023 through 31 December 2023. Phase 1 will be development of CCHD eLearning modules. Phase 2 will study the effect of CCHD specific eLearning modules versus directed CCHD readings (figure 1). Target audience and participants will include NRP-trained HCPs involved in the DR resuscitation of neonates with CCHD, including physicians, paediatric/neonatal trainees, advanced practice providers, nurses, and respiratory therapists.

![Flow diagram of the randomised simulation team testing](image)

**Figure 1** Flow diagram of the randomised simulation team testing. CCHD, critical congenital heart defect; HLHS, hypoplastic left heart syndrome; IVS, intact ventricular septum; NASA-TLX, NASA Task Load Index; NRP, neonatal resuscitation programme; TGA, transposition of great arteries.
neonatal nurses (registered nurses (RNs), including those with specialised skill sets such as transport nurses) and respiratory therapists (RTs).

**Recruitment, randomisation and educational interventions**

Participants will be recruited from all eligible HCPs from each site. Each site is a member of the Children’s Hospitals Neonatal Consortium, a multicentre collaborative of 46 level IV neonatal intensive care units (NICUs) in Children’s Hospitals in the USA and Canada dedicated to developing quality and research initiatives across participating institutions. Participating NICUs have greater than 400 annual admissions or greater than 25 NICU beds, and greater than 50% outborn infants. Annual deliveries of congenital heart patients at the participating site ranges from 30 to 100 per year. Each site either has its own delivery unit or partners with a level III NICU that delivers high-risk infants.

Participation will be voluntary. Informed consent will be obtained. Prior to randomisation, participants will complete a prestudy demographic questionnaire to obtain profession, years of experience, level of experience in the DR, NRP and paediatric advanced life support training levels and prior experience with infants with CCHD. This information will be used to create teams and stratify team leaders for DR and CCHD experience.

Participants will be organised into simulation teams of three with a team leader and two team members, mirroring standard delivery team compositions (eg, physician/advance practice provider (APP) as leader, RN/RT as assistants). Strata will be placed in an opaque envelope, and names will be randomly drawn by an assistant not involved in the study to randomise participants to intervention arm. Participants will complete the knowledge pretest questions (online supplemental file 1) prior to educational arm assignment. According to their randomly selected team, participants will then be sent an electronic link to access either CCHD eLearning or CCHD directed readings 1 week ahead of the scheduled simulation sessions with instructions for individual assignment completion. All participants will additionally receive a short NRP refresher module. Completion of the learning modules will be tracked via completion of poststudy survey administered via RedCap with a concurrent postintervention knowledge assessment as well as a survey assessing the acceptability of the educational intervention, targeted CCHD eLearning module or CCHD directed readings (online supplemental file 2). Within 1 week of completion of their assigned education, participants will complete standardised DR simulations.

**Phase 1: development of educational modules and clinical scenarios – eLearning modules**

Four eLearning modules will be developed to address the resuscitation of CCHD in the DR. The topics covered will include the review of fetal to neonatal transition and introduction to CCHD, and three specific cardiac diseases (TGA-IVS, HLHS and third-degree heart block). These three cardiovascular complications were chosen because they each confer increased risk for haemodynamic instability in the immediate postnatal period and require lesion-specific DR knowledge or interventions to address unique cardiovascular pathophysiology (table 1).

E-learning modules will be succinct and high-yield to

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Planned critical congenital heart defect delivery room management learning modules</th>
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<td>Module</td>
<td>Learning objectives</td>
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| Fetal to neonatal circulation transition | ► Understand fetal and neonatal circulation  
► Describe the changes in neonatal circulation at time of birth  
► Outline normal newborn circulation |
| Arrhythmias | ► Describe common arrhythmias presenting in immediate newborn period  
► Describe complications of fetal arrhythmia in utero  
► Understand the criteria for haemodynamic significant arrhythmias  
► Outline the steps in management of congenital third degree heart block in delivery room |
| HLHS (single ventricle) | ► Understand single ventricle physiology and lesions  
► Describe the importance of atrial level shunt and ductus arteriosus in postnatal management of single ventricle  
► Understand the modification in targeted oxygen saturation goals in delivery room for patients with single ventricles  
► Understand the role of prostaglandin and common side effects |
| Transposition of great arteries | ► Understanding the physiology of TGA in fetal and neonatal circulation  
► Recognise the importance of unrestricted atrial septum and patent ductus arteriosus for fetal to neonatal transition  
► Understand the criteria for haemodynamic compromise  
► Outline the delivery room management of TGA with restrictive atrial septum, including recognition of the need for emergent referral to balloon atrial septostomy (BAS) services if unstable or unresponsive cyanosis |

HLHS, hypoplastic left heart syndrome; TGA, transposition of great arteries.
address adult learning needs, focusing on clinically relevant lesion-specific information pertinent to immediate DR management and to outline suggested cardiac lesion-specific modifications to NRP algorithms. Lesion-specific adaptations to NRP include elements as (a) modified CCHD specific oxygen saturation targets and considerations for administration of supplemental oxygen, (b) need to maintain ductal-dependent circulation with initiation of prostaglandin infusion with requisite monitoring for drug side effects (eg, apnoea), (c) clinical haemodynamic assessment for haemodynamic instability and cardiogenic shock requiring emergent consideration for balloon atrial septostomy (BAS) and (d) additional clinical assessment for haemodynamic instability requiring initiation of heart rate control (eg, congenital third degree heart block) (table 1).

Each module will be designed to take approximately 15 min to complete and follows a similar format including: (a) overview of the specific CCHD, (b) DR prebrief questions to review, (c) prenatal findings to evaluate risk for immediate postnatal haemodynamic instability, (d) when to consider the particular CCHD without any prenatal diagnosis, (e) the clinical presentation, (f) management steps in the DR and (g) contingency or integration of potential known adaptions to the NRP algorithm to consider. An additional 5–10 min is allotted for reflection or review for each online module; therefore, the total time anticipated for the eLearning experience is 1.5–2 hours. Modules will first be piloted for content and usability by one site (Boston Children’s Hospital). Pilot feedback will be evaluated and incorporated into eLearning modules prior to finalising eLearning modules for the study.

Directed CCHD reading

For the comparison education intervention, the research team reviewed and selected three articles by consensus to be distributed for use as directed CCHD literature. These articles contain the information to be taught in the eLearning modules relevant to resuscitation of neonates with CCHD but require the reader to independently dissect out information relevant for DR management and individual/team roles. It will take a minimum of 1.5–2 hours for an HCP to read and reflect on the selected literature as it does to complete the eLearning modules, keeping time equivalence as a controlled variable. These articles are easily identified in a literature search using search words “delivery” and “congenital heart disease” or “transposition of the great arteries” and “neonate” and “arrhythmias” using Medline or PubMed search engines; thus, they may be used by clinicians as reference sources in preparation for a CCHD delivery, serving as a good comparator. The references will be shared with each participant if they are randomised to the directed CCHD readings.

Phase 2: evaluation of education interventions

The eLearning modules will be evaluated in a randomised study using a combination of (a) individual HCP pre-exposure and postexposure knowledge testing and (b) team-based postexposure simulation testing. Educational methodology acceptability will also be measured and compared. This will enable us to compare the eLearning modules with directed readings on different levels of Kirkpatrick’s schematic.

Design and pilot-testing of CCHD simulation scenarios

Three clinical simulations will be designed to test the specific CCHD educational modules’ ability to instruct HCPs to integrate CCHD specific steps into the DR management. One additional standard NRP (non-cardiac) scenario will be designed to test standard resuscitation performance for both groups. All simulations will be scripted with standardised stems, starting and transitional phases as well as standardised cues or prompts. Standardised checklists of actions and time-based events will be designed in concert with the simulation scenarios to permit reviewers to compare errors and time to interventions from video recordings of the simulations. Simulation scenarios and checklists will then undergo pilot testing using HCPs not involved in the study design and not recruited as participants for usability and reproducibility.

Study setting

The study will be performed at 10 sites affiliated with level III NICUs in Canada and the USA. Simulations will be conducted in situ at each site using high-fidelity simulation equipment and video recording. Video equipment, simulation fidelity and access to resuscitation equipment will be standardised across sites prior to testing. Each recruiting site and team will describe their hospital’s experience and volume of CCHD deliveries. Team members will fill in a demographic survey to facilitate team assembly and randomisation.

Recruitment and study procedures

Inclusion criteria for eligibility to participate include HCPs who have completed NRP training within the last 2 years and routinely attend deliveries, including physicians (neonatologists, paediatricians, paediatric hospitalists, neonatal-perinatal medicine subspecialty fellows, paediatric residents), APPs, RNs (including those with specialised skill sets such as transport nurses) and RTs. Both HCPs with and without extensive DR experience with resuscitation of neonates with CCHD will be included. A minimum sample size of 36 teams will be used with a goal of 60 teams. Power analysis is outlined below. A minimum of two teams will be recruited from each participating site. Using teams of three, we anticipate recruiting 180 individual HCPs. HCPs who have participated in the initial development and evaluation phase of the eLearning modules will also be excluded.
OUTCOME MEASURES

Primary endpoint
The primary outcome of the study is composite total errors, measured by checklist scores for all three cardiac scenarios. The checklists scores are available in online supplemental file 3.

Secondary endpoints
1. Individual HCP preintervention versus postintervention comparison:
   a. Pre-educational and posteducational intervention assessment of CCHD DR management knowledge.
2. Individual HCP perception of educational interventions.
   a. Education intervention acceptability survey.
   b. Survey for user accessibility.
   a. Errors for each scenario as measured by specific scenario-based performance checklists.
   b. Total CCHD scenario specific errors for all CCHD scenarios.
   c. General NRP scenario errors for all CCHD scenarios.
   d. Errors in standard NRP scenario on abortion.
   e. Time to predefined, time-critical interventions based on the scenario:
      i. Standard NRP scenario (abruption): time to start positive pressure ventilation (PPV) for complete apnoea, time to chest compressions for heart rate <60 bpm after establishing adequate ventilation, time to delivery of volume.
      ii. HLHS scenario: time to start PPV for complete apnoea secondary to prostaglandin.
      iii. TGA-IVS scenario: time to activation of additional specific cardiac resources (eg, call for transport to site for BAS assessment or activate cardiology team for BAS) as progressing through NRP algorithm without ability to improve patient’s oxygenation.
      iv. Third degree congenital heart block scenario: time to start additional intervention to increase heart rate after determining (or being cued about-standardised to scenario) cardiovascular instability.
   f. Teamwork metrics
      i. Composite TEAM assessment score of all three CCHD scenarios in online supplemental file 4.
      ii. TEAM assessment score for each scenario.
   g. Composite NASA-Task Load Index (NASA-TLX) for simulation session for: (i) team leader, (ii) assistants and (iii) team total.

Simulations
All teams will complete four simulations, representing (a) standardised NRP DR NRP scenario, (b) HLHS requiring modification of targeted saturations and intervention for apnoea secondary to prostaglandin, (c) TGA-IVS with restrictive atrial septum requiring stabilisation and recognition of the need for BAS, (d) congenital heart block with signs of cardiovascular instability. The standard NRP scenario will serve as an orientation simulation for the team, orientation to the simulation environment, and as a standard assessment of NRP performance.

Due to the complexities of the scenarios, participant teams will be assisted by one standardised ‘confederate’, who will be available to perform additional procedures as needed (eg, obtaining intravenous access, call for additional resources, etc). For each scenario, confederates will also ask additional, predetermined questions that are aimed at (a) probing the team’s understanding of the CCHD specific NRP adaptations (eg, asking to aim for normal NRP saturation goals in the resuscitation of a patient with HLHS or TGA-IVS, asking to jump to chest compressions when the heart rate is less than 60 bpm in congenital third degree heart block) or (b) providing time determined prompts if a critical step is yet to be done and required for a time determined variable (ie, start prostaglandin for HLHS to allow for assessment of team recognition and response to apnoea). Confederates would otherwise not provide any additional information or guidance outside of their assigned tasks.

After completing all four simulations, HCPs will complete a survey to assess the realism of the simulations and inquire about their subjective workload (NASA-TLX). Finally, teams will be debriefed by simulation facilitators using a plus-delta model. Debriefing of all scenarios will be conducted at the end of the entire simulation session to avoid contaminating simulation performance.

Simulation performance evaluation and analysis
Once simulations have been completed, videos will be assessed by two independent raters blinded to intervention group and who did not facilitate or participate in the simulations. This will determine: (a) CCHD specific and general NRP errors, (b) time to predetermined time critical interventions and (c) teamwork assessment using TEAM score. Both CCHD and general NRP errors will be predetermined, with assessments standardised using an NRP checklist modified for each simulation scenario.

For each scenario, time to prespecified critical interventions, defined by time from predetermined ‘time zero’ to predetermined medical intervention, will be measured. As an example, the time to start PPV for prostaglandin induced apnoea is measured from a time zero of respiratory rate=0 on manikin to when first PPV breath is given by a team member. TEAM assessment will be done for each scenario using the TEAM checklist. Prior to reviewing the videos, raters will be standardised for the modified NRP checklists, TEAM assessment, and predetermined time to critical interventions. The raters will independently score previously recorded scenarios (not related to the study) demonstrating below average, average and above average team performance and then debrief until good inter-rater reliability is achieved.
STATISTICAL METHODS

Sample size calculations
Previously published observational and simulation studies using mega-code checklists to evaluate performance demonstrated mean scores of 80%–90%, with SD ranging from 5% to 15%. Approximating a mean checklist score of 90%, with an SD of 7.5%, a sample size of 36 teams will detect a 5% difference in checklist scores with a power of 0.8 and an alpha of 0.05. Given the complexity of the scenarios, approximating a lower mean checklist score of 80%, with an SD of 15%, a sample size of 36 teams will detect a 10% difference with a power of 0.8 and an alpha of 0.05.

Analysis
The data will be presented as mean (SD) for normally distributed continuous variables and median (IQR) when the distribution is skewed. Comparisons between the two groups will be performed using Student’s t-test for parametric data and Mann-Whitney U for non-parametric data. Correlations will be performed using Pearson’s correlation coefficient for parametric data and Spearman’s rank correlation coefficient for non-parametric data. Statistical analysis will be performed using SPSS V.29 (IBM Corp., Armonk, USA).

Data management
Participant demographics will be collected in a standardised format (data collection forms approved by the research ethics boards at all participating sites) and stored in a password protected electronic file on a secure server at the data coordinating centre. For the purpose of confidentiality, the data are entered using the participant’s study number. All identifying information will be removed prior to data analysis. A separate log will be maintained linking the study number to the HCP identifying information. Only the study coordinator at each site has access to this file.

Patient and public involvement
A range of stakeholders and partners have been actively involved in the design and conduct of this observational study including HCPs in participating NICUs, paediatric cardiologists, members of the fetal heart society, RTs and neonatal nurses. Their input was sought during protocol design regarding the selection of the eModules most suitable for clinical translation and their potential for enhancing overall education. All stakeholders and partners are updated at regular intervals about the study’s progress to identify facilitators and barriers to study conduct and knowledge translation. Following study completion, we plan to discuss future directions, including a multi-centre clinical trial based on study findings, in consultation with neonatologists, paediatricians, cardiologists, healthcare practitioners and parent-led community groups.

Ethics approval and informed consent
This study was approved for the coordinating site (University of Texas Southwestern) by the Research Ethics Board at University of Texas Southwestern on DATE (IRB# STU 2021-0457). Documented approval was obtained from the Research Ethics Board/Institutional Review Board for all participating centres prior to participant enrolment at that centre. Once all questions are answered and participants confirm their understanding of study procedures, participants are invited to provide voluntary written informed consent.

Dissemination of results
All coauthors will facilitate knowledge dissemination among key stakeholders including neonatologists, cardiologists and clinician-investigators, providing the network necessary to support future multi-centre randomised clinical trials. As done previously, we will work with national child health advocacy organisations, using our research findings to drive evidence-informed changes in clinical practice. The results of this study will also be disseminated in a lay format and communicated to a wider scientific and healthcare community through end of study meetings, presentations at national and international paediatric and critical care conferences, and high-impact peer-reviewed publications. Information regarding the use of specific eModule to enhance education in the DR will be shared with clinicians across various disciplines including neonatologists, cardiologists, trainees, developmental paediatricians and other community-based HCP. Study results are also intended to be shared with AHA and AAP. Finally, these findings will be communicated to policy makers to identify priority areas of care, to reduce burden on families and to reduce costs to the healthcare system by organising tailored follow-up services for these neonates.

Anticipated limitations
Use of a multi-centred design will help increase the pool of potential participants allowing recruitment from smaller centres. To account for different levels of individual and institutional experience with CCHD, we aim to recruit at least two teams per site, attempt to match team leader experience within sites during stratified randomisation, as well as the frequency of these types of deliveries for each institution. There are variations in institutional practices and access to resources (eg, perform BAS vs transfer to hospital with these capabilities). To account for this, simulations and assessment checklists will be developed with inborn and out born centre neonatologist input. Finally, only short-term HCP performance and acceptance of the educational intervention will be assessed due to funding and logistics constraints to assessment of long-term retention.

Future directions and relevance
Future directions could include a repeat of the simulations at 3 and/or 6 months to assess for retention. Additional educational resources that explore CCHD and prematurity interactions could be provided. While infants are often managed after the DR resuscitation in centres...
with cardiac expertise, deliveries occur across many sites with different levels of CCHD experiences and different NRP educational infrastructures and resources. Online eLearning modules specific to DR management of infants with CCHD will provide a readily accessible educational resource for practitioners of all disciplines and experience, including the many peripheral sites that deliver babies with undiagnosed CCHD. Simulation testing will not only validate these educational modules, but also provide insight into the types of errors committed by HCPs in the DR resuscitation of infants with CCHD, helping to focus future educational initiatives. Finally, we also plan to develop additional eLearning modules targeted at additional congenital heart lesions that HCP face in the DR (eg, Ebstein’s, CoaTion of the aorta, Tetralogy of Fallot with absent pulmonary valve, etc).

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Contributors NA is the lead coordinator overseeing all study sites and is responsible for all patient recruitment and acquisition of data in Texas. PL, AT, BL, CJ, RG, SE, DR, LRP, BAJ, MB, SG and JS are the principal investigators at their respective sites and were all extensively involved in the study concept, design and completion of echocardiographic assessments. NA, PL, AT, BL, CJ, RG, SE, DR, LRP, BAJ, MB, SG and JS are involved in the development of the analysis plan. All the authors have extensively reviewed the protocol/final manuscript. All authors read and approved the final manuscript.

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REFERENCES

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