Executive Summary: CCHD Subcommittee Findings 2017-2020

In October 2017, the Newborn Screening Advisory Committee (NBSAC) discussed critical congenital heart disease screening in Texas and posed the question, “How can we assure that all newborns are screened?” To address this question, the CCHD Subcommittee was formed to provide advice to the Commissioner regarding how the newborn screening program can assess and improve the quality of this aspect of the Texas Newborn Screening System.

Since then, the CCHD Subcommittee has met several times and presented a number of items to the NBSAC. A summary was provided to the NBSAC as a separate document in October 2019.

The primary impediment to evaluating the quality of CCHD screening in Texas is the Health and Safety Code (https://statutes.capitol.texas.gov/Docs/HS/htm/HS.33.htm), which mandates this point-of-care screening procedure but requires the reporting only of confirmed cases. Without fundamental data, the quality of the CCHD newborn screening procedure cannot be determined in Texas, and improvements will not occur. Records of reported cases over a three-year period illustrate that identification of cases may vary significantly across different regions. Moreover, comparison with the Texas Birth Defects Registry (TBDR) indicates that less than one out of every 5 newborns with CCHD is reported to the Newborn Screening system, as required by statute. Consequently, the charge to the CCHD Subcommittee was amended to include recommendations on a) how to improve reporting of positive cases, and b) “best practices” for CCHD screening in Texas.

Several Draft Recommendations have been considered:
1. The Texas Administrative Code should be changed to allow for newborn screening data to be sent to the Newborn Screening Program.
2. The Texas Administrative Code should be amended to clarify responsibility for CCHD reporting.
3. The Texas Department of State Health Services should develop and support a network of community champions to educate and motivate those responsible for CCHD screening and reporting to follow best practices.

The first recommendation has not received consistent support from the Subcommittee because of fear that opening the Administrative Code to this change may result in additional alterations that would potentially create difficulties elsewhere in the newborn screening system. In addition, The NBS Program’s submission of a legislative initiative in November 2019 for making legislative changes to the Health and Safety Code for CCHD was not approved to move forward.

The aim of the second recommendation may be feasible, because the Health and Safety Code, Section 33.15, uses broad language and therefore might be elaborated upon in rule.

The third recommendation has been discussed extensively, but specific aspects have not been developed. Considerations have included collaboration with the Regional Advisory Councils (RACs) and Texas Collaborative for Healthy Mothers and Babies (TCHMB). Dr. Speer planned to bring up this issue with the Executive Committee of the Perinatal Advisory Committee in January 2020.

Critical Congenital Heart Disease (CCHD) Subcommittee
Meeting Minutes
July 10, 2020
4:00 p.m.

Conference Call

Table 1: Critical Congenital Heart Disease (CCHD) Subcommittee member attendance at the Friday, July 10, 2020 meeting.

MEMBER NAME	IN ATTENDANCE
Scott McLean, M.D. (Subcommittee Chair)	BY PHONE
Alice Gong, M.D. (Ex-officio)	BY PHONE
Tiffany McKee-Garrett, M.D.	NO
Joseph Schneider, M.D.	BY PHONE
Michael Speer, M.D. (Ex-officio)	BY PHONE

Table 2: Subject Matter Expert (SME) attendance at the Friday, July 10, 2020 meeting.

SUBJECT MATTER EXPERT NAME	IN ATTENDANCE
Donna Goff, M.D., M.S.	BY PHONE
Carriston Hendricks, M.S.N.-F.N.P.	BY PHONE
Elena Ocampo, M.D.	NO

Table 3: Newborn Screening Unit (NBS) Staff attendance at the Friday, July 10, 2020 meeting.

NBS STAFF MEMBER NAME	IN ATTENDANCE
Laura Arellano	BY PHONE
Debra Freedenberg, M.D., Ph.D.	BY PHONE
Karen Hess	BY PHONE
David R. Martinez	BY PHONE
Aimee Millangue	BY PHONE

PREVIOUS SUBCOMMITTEE BUSINESS

The Critical Congenital Heart Disease (CCHD) subcommittee last met by conference call on January 10, 2020 and reported to the full committee at the January 31, 2020 Newborn Screening Advisory Committee (NBSAC) meeting.

At the January 31 meeting, NBSAC members discussed:

- Birth defects can do case level information for babies that have been screened for CCHD
- Individual hospital systems reporting to a repository
- Manual input for electronic medical records by midwives

SUBCOMMITTEE MEETING NOTES

Dr. Scott McLean, Chair of the Critical Congenital Heart Disease (CCHD) Subcommittee, convened the meeting at 4:02 p.m. Dr. McLean greeted everyone. Ms. Aimee Millangue, DSHS, Newborn Screening Unit, Advisory Committee Support, reviewed logistics and attendance. The meeting was held via conference call and was audio recorded.

Subcommittee Meeting Discussion:

- Reviewing the subcommittee's prior work, included in the Executive Summary document emailed to subcommittee members
- Outstanding action items
    - Follow up from Dr. Michael Speer on consulting with the Executive Committee of the Perinatal Advisory Council (PAC) at their meeting January 13, 2020 regarding CCHD reporting as a hospital Quality Improvement (QI) initiative with the Texas Collaborative with Healthy Mothers and Babies (TCHMB) and Regional Advisory Councils (RACs)
        - Dr. Speer reported that idea was not picked up by the PAC, but he will follow up with additional contacts at TCHMB
- Reviewing recent publications on CCHD:
    - Martin et al. Updated Strategies for Pulse Oximetry Screening for Critical Congenital Heart Disease, 2020.
        - A consensus group of subject matter experts are recommending a different algorithm for CCHD Screening from what is currently in the DSHS CCHD toolkit
        - Recommended algorithm has not yet been adopted into policy by the American Academy of Pediatrics (AAP)
        - Recommendation that for babies that are identified through the Birth Defects Registry, it is verified that they had a CCHD screening and that it was done properly
    - Campbell et al. Pulse Oximetry Screening Has Not Changed Timing of Diagnosis or Mortality of Critical Congenital Heart Disease, 2020.
        - Written by cardiovascular surgeons and cardiologists at Children's Hospital of Philadelphia (CHOP)
        - CHOP is a referral center with most patients prenatally diagnosed, which influences their data
        - Prenatal diagnosis rates vary by facility and region, which impacts what is missed and picked up through CCHD screening
    - Oster and Martin. Newborn Screening for Critical Congenital Heart Disease: Appropriately Evaluating This Public Health Program, 2020.
        - Response to CHP article defending CCHD screening
- Transition to another chair of the subcommittee, as Dr. McLean's term as a member of the NBSAC is drawing to a close
- Draft Recommendations
    - Revisiting change in Rule to have reporting of data and positive diagnosis
        - May not want to go to Legislature again when CCHD screening legislation was already passed

        - System infrastructure still a challenge for reporting CCHD data
        - Process may need to rely on a centralized reporting system, but also a challenge when patients are referred to other facilities
        - DSHS may be able to identify costs for a centralized system and look into Rule language in a future legislative session
        - Texas is among 20% of states that do not receive CCHD data
        - Data would help identify program improvement opportunities to monitor the impact of early identification using CCHD screening
            - Texas Pulse Oximetry Project (TxPOP) was a pilot project with deidentified data conducted concurrently with CCHD legislation
            - Feasibility of a new pilot project through the Newborn Screening (NBS) Program to demonstrate that the program could receive individual level data and asses its quality and make improvements to the state NBS system
            - Feasibility of grant-funded private initiative to set standard of care
    - Proposing CCHD Reporting as a QI project for hospitals through RACs
        - Have hospitals shoot for 100/95% of babies screened and produce data to show it
        - Drafting a recommendation letter to ask DSHS Commissioner Dr. John Hellerstedt to recommend CCHD reporting as a QI project to TCHMB to measure if all babies are being screened
            - Data could be reported in the same way as hearing screening data by setting a threshold and grading them
        - Current incidence rate through screening affected by underreporting of CCHD screening based on data from Birth Defects Registry

ACTION ITEMS:

- Dr. Speer will contact members of TCHMB to propose CCHD Reporting as a QI project for the RACs
- Dr. Speer and Dr. Alice Gong will work on a draft recommendation letter to send to Dr. Hellerstedt, with a possible goal of presenting at the July 30, 2020 NBSAC meeting or the next

Ideas/Next Steps:

- NBSAC Chair Dr. Gong has invited Dr. McLean to stay on the subcommittee as a Subject Matter Expert
- Looking into feasibility of a recommendation to Birth Defects Registry to check records for CCHD screening prospectively
- Annual review of CCHD cases reported through the Birth Defects Registry and the percentage of those cases that were identified through CCHD screening

Dr. McLean adjourned the meeting at 4:58 p.m.

July 15, 2020

Dr. John Hellerstedt, Commissioner
Texas Department of State Health Services
PO Box 149347
Austin, Texas 78714-9347

Dear Dr. Hellerstedt,

In 2017, the Newborn Screening Advisory Committee (NBSAC), in response to parental concerns about critical congenital heart disease (CCHD) screening, posed the question as to how to assure that all Texas newborns are screened for CCHD as mandated by HB 740, 83rd legislature regular session in 2013. To address this question, a CCHD subcommittee was formed to provide advice regarding how the Texas Newborn Screening Program can assess and improve the quality of CCHD screening. The subcommittee has met many times and has provided a summary to the NBSAC.

Texas Health and Safety code Rule 37.75 only requires that confirmed cases of CCHD be conveyed to Department of State Health Services. This rule does not allow for oversight and thus quality improvement of this point of care screen. Records of reported cases thus far illustrate that reporting is extremely variable across the state. The Texas Birth Defects Registry (TBDR) has informed the Subcommittee that, during their active surveillance over 17 years, there were approximately 700 cases of CCHD per year. Using current reporting methodology, only 513 cases were reported to the Department of State Health Services from September 2014 to June 2018. Thus, Texas hospitals are either under-reporting, not testing, or not testing appropriately.

The Subcommittee, after discussion, developed three recommendations for consideration by the NBSAC: 1. The Texas Administrative Code be changed to allow for newborn screening data to be sent to the Newborn Screening Program. 2. The Texas Administrative Code be amended to clarify responsibility for CCHD reporting. 3. The Texas Department of State Health Services develop and support a network of community champions to educate and motivate those responsible for CCHD screening and reporting to follow best practices.

Regarding the first recommendation, which would substantially change the logistics and costs of the point-of-care CCHD screening, the subcommittee could appreciate many advantages and many disadvantages, and at the present time, have decided to defer endorsing this recommendation. The second recommendation, regarding clarifying and improving the reporting of confirmed cases, might be feasible via an amendment in the rules. The subcommittee favored the third option. As you know, levels of care designation of maternity and newborn services have resulted in the formation of Regional Advisory Councils (RACs) that are responsible for undertaking quality improvement projects. In addition, the RACs have joined with Texas Collaborative for Healthy Mothers and Babies (TCHMB) whose mission is to improve the health of Texas mothers and babies. Therefore, a quality improvement project on

CCHD screening could be undertaken by the RACs without changes to the Administrative Code. This would allow the state to determine whether hospitals are screening, if they are screening appropriately and if they are reporting in a timely manner.

The Subcommittee asks that the Department of State Health Services support the NBSAC by asking TCHMB and the RACs to consider using CCHD screen as a quality improvement measure. Thus, we could be assured that each and every baby receives this life-saving screen appropriately. As always, thank you for your support of the Texas Newborn Screening Program.

Respectfully,

Alice Gong
Michael Speer
Scott McLean.