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Impact of Expansion in Newborn Screening on Hospital Performance and Provider Perceptions in Georgia

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Abstract

Impact of Expansion in Newborn Screening on Hospital Performance and Provider Perceptions in Georgia

By Shelby T. Rentmeester

In 2011, the U.S. Secretary of Health and Human Services recommended universal screening for CCHD; in response, the Georgia Department of Public Health (GA DPH) mandated routine screening for CCHD starting January 2015. The GA DPH also mandated screening and reporting of hearing loss for all infants. Utilizing the PRECEDE-PROCEED Model, the current study evaluated the impact and process for completing the new screens and reporting the results to the GA DPH using the Newborn Screening Specimen Card (NBS Card). Utilizing the GA DPH active surveillance system for newborn screening results, data from six months before and six months after the transition to the updated NBS Card were analyzed for percentage submitted and for percentage positive screens. Hospitals with Level III nurseries and cards submitted by a Neonatal Intensive Care Unit (NICU) had the lowest rates of reporting the results of each test to the GA DPH. Of the infants that were screened, NICUs had higher rates of positive screens. If all unscreened NICU admissions had been screened for CCHD and hearing loss, an estimated 33 additional infants would have screened positive for CCHD and 267 would have been referred for hearing loss. For the process evaluation, a survey was developed and sent to nurse managers of all Labor and Delivery hospitals. Forty-nine nurse managers responded to the survey (response rate of 62.8%). The majority of respondents indicated that the NBS Card was not confusing to complete and it does not take time away from providing the best care to patients, but over half of the respondents indicated that the card does not impact providing the best care. Increased reporting help to identify the true burden of disease in Georgia, which can better inform medical interventions and health policy.

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Table of Contents

Abbreviations

CHD – Congenital Heart Defect
CCHD – Critical Congenital Heart Defect
CI – Confidence Interval
GA DPH – Georgia Department of Public Health
IRB – Institutional Review Board
NBS Card – Newborn Screening Specimen Card
NICU – Neonatal Intensive Care Unit
OR – Odds Ratio
PPM – PRECEDE-PROCEED Planning Model
PRECEDE – Predisposing, Reinforcing, and Enabling Constructs
PROCEED – Policy, Regulatory, and Organizational Constructs
χ^2 – Chi Square value

Chapter I Introduction

Background

Approximately one in 33 infants is born with a birth defect; congenital heart defects (CHD) are the most prevalent birth defect (CDC, 2015). CHD impact the structure and function of the heart. These defects range in severity and approximately one in four CHD is considered a critical congenital heart defect (CCHD). Each year in the United States, roughly 7,200 infants are born with a CCHD (Reller, Strickland, Riehle-Colarusso, Mahle, & Correa, 2008). Critical congenital heart defects can be life threatening and are characterized by the need for surgery or catheter intervention during the first year of life (Mai et al., 2012). Specific CCHDs include: coarctation of the aorta, double-outlet right ventricle, d-Transposition of the great arteries, Ebstein anomaly, hypoplastic left heart syndrome, interrupted aortic arch, pulmonary atresia (with intact septum), single ventricle, total anomalous pulmonary venous return, tetralogy of Fallot, tricuspid atresia, and truncus arteriosus (CDC, 2015).

Though the long-term outcomes for children with CCHD have been improving over the past decades, delayed screening can have a negative impact for health outcomes (Oster, Lee, et al., 2013). Screening for CCHD varies across the United States based on regulations imposed by the individual states. Prenatal ultrasounds have been used to detect certain CCHDs, but miss others (American Academy of Pediatrics). Utilization of pulse oximetry after delivery increases the likelihood of detecting CCHD before the newborn is discharged from the hospital and can shorten the time to intervention (American Academy of Pediatrics). Pulse oximetry involves placing a clip-like, medical device on the infant's right hand and foot; this will measure the oxygen level, or oxygen

saturation, of the blood (Pulse Oximetry, 2016). Recommendation for implementing a pulse oximetry protocol for CCHD screening in the United States was constructed based on a Swedish study (de-Wahl Granelli et al., 2009). Compared to the previous standard of a physical examination, pulse oximetry reduces the percentage of false positives and increases the likelihood of detecting the CCHD (de-Wahl Granelli et al., 2009).

In 2011, the U.S. Secretary of Health and Human Services officially recommended universal screening for CCHD by pulse oximetry (Sebelius, 2011). This recommendation is based on the results of a work group selected by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, the American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association (Kemper et al., 2011). The purpose of this screening is to detect CCHD in infants who may appear to be healthy, but have low oxygen levels. As of December 2014, 43 states have legislation, regulations, or hospital guidelines that support CCHD newborn screening (Glidewell et al., 2015).

Problem Justification

In June 2012, the Centers for Disease Control and Prevention along with the Georgia Department of Public Health (GA DPH) assessed the current practices and feasibility of implementing CCHD routine screenings (Clark et al., 2013). This assessment consisted of a survey delivered to all labor and delivery hospitals in Georgia with questions about current practices and interest in implementing a routine screening procedure for CCHD. Results from this assessment indicated that the majority of hospitals in Georgia either had protocols in place for routine screening or had a plan to start in the near future (Clark et al., 2013). For hospitals screening for CCHD at the time

of the survey, only one-third were following the protocol endorsed by the American Academy of Pediatrics, the American College of Cardiology and the American Heart Association (Clark et al., 2013).

Results from this assessment were used to develop and pass a statewide regulation, Georgia rule Subject 511-5-5, effective June 2014. This rule provides administrative details and procedures for the testing of inheritable disorders in newborns (Ga. Comp. R. & Regs. r. 511-5-5-.01). Full rule Subject 511-5-5 can be found in Appendix A. Written guidance includes how to use the Newborn Screening Specimen Card (NBS Card) to collect specimens, process the specimens and provide data to the GA DPH. Subsequent updates for this rule section include the instructions on systematic screening for CCHD and completion of a test to determine the infant's hearing status.

Theoretical Framework

This study utilizes guiding principles from the PRECEDE-PROCEED planning model (PPM). The PRECEDE (Predisposing, Reinforcing, and Enabling Constructs) model, focuses on the designing of interventions that strategically addresses demonstrated needs (Gielen, McDonald, Gary & Bone, 2008). In 1991, PROCEED (Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development), was added to the model (Gielen et al., 2008). The full model incorporates eight phases: four for planning, one for implementation, and three for evaluation (see Appendix B for figure).

PRECEDE incorporates the first four phases of assessments of: 1) social norms, 2) epidemiology, behaviors and environment, 3) education and ecology, and 4) policy (Gielen et al., 2008). Phase one, social assessment, participatory planning, and situational

analysis, informs intervention designers on the community and its values. Phase two, epidemiological, behavioral, and environment assessments, identifies priorities for health issues and their behavioral and environmental determinants (Gielen et al., 2008). Phase three, educational and ecological assessment, incorporates three types of factors: predisposing, reinforcing and enabling factors. These factors help to build the capacity to sustain the behavior change addressed by the intervention. The final phase for PRECEDE, administrative and policy assessment and intervention alignment, identifies the necessary resources and any organizational or policy barriers that need to be address for the implementation of the intervention (Gielen et al., 2008).

After the planning phases have been addressed and the results inform intervention development, phase five, program implementation, can occur (Gielen et al., 2008). The final three phases involve evaluating the process, impact and outcome of the intervention. Process evaluation determines the extent to which the intervention was implemented according to protocol (Gielen et al., 2008). Impact evaluation assesses the changes imposed upon phase two and three factors. The final evaluation, outcome, determines the effect on general quality of life indicators.

Purpose – Program evaluation

According to the PPM, the first five steps of adding CCHD and hearing screening to routine newborn screening protocols in Georgia have been completed. The purpose of the current study is to evaluate the impact of the updated NBS Card for labor and delivery hospitals in Georgia on CCHD and hearing screening results, completing phase seven according to PPM. This study will also conduct a process evaluation, phase six, to

investigate the provider perceptions and hospital procedures surrounding the implementation of the NBS Card and reporting the results to the GA DPH.

Research Questions

1. Is the level of newborn unit (i.e. regular or neonatal intensive care [NICU]) providing the NBS Card associated with the proportion of unsatisfactory NBS card submissions?
2. Is the implementation of the NBS Card associated with reported prevalence of CCHD in Georgia?
    a. Is the level of unit providing the results associated with reports of CCHD screening?
3. Is the implementation of the NBS Card associated with reported prevalence of referrals for hearing loss in Georgia?
    a. Is the level of unit providing the results associated with reports of hearing loss screening?
4. What do providers perceive in regards to the process and impact of newborn screening and reporting the results?

Chapter II Literature Review

Introduction

Delayed detection, typically defined as detection of CCHD after initial discharge, is associated with various adverse developmental outcomes and mortality (Dawson et al., 2013). Before the implementation of CCHD screening pulse oximetry protocols across the United States in 2011, physicians relied solely on prenatal ultrasound techniques and physical symptoms at delivery (Olney, Ailes, & Sontag, 2015). Ultrasound methods include a four-chamber view of the heart and, if possible, views of the outflow tracts to monitor structural heart defects; however, abnormalities with outflow tracts are less likely to be detected (Olney et al., 2015). Higher detection rates were associated with higher-risk pregnancies such as those with maternal diabetes and a familial history of CCHD, due to the increased use of ultrasounds during these pregnancies (Olney et al., 2015). The expansion of newborn screenings to include universal CCHD screening was driven by the realization that prenatal detection was incomplete as well as the importance of early detection for reducing morbidity and mortality associated with undiagnosed CCHD (Olney et al., 2015).

Background & Significance

The American Academy of Pediatrics has recommended procedures for implementing the CCHD screening protocol (W. T. Mahle et al., 2012). The purpose of the screening is to identify infants who do not show physical symptoms of CCHD, but have abnormal oxygen levels (W. T. Mahle et al., 2012). Screening should ideally occur 24 hours after birth and readings should be obtained on the right hand and on one foot; if an infant is scheduled to be discharged before 24 hours, the screening should occur as late

as possible (W. T. Mahle et al., 2012). A pulse oximetry reading above 95% Oxygen Saturation would be considered a pass, but this reading should be adjusted depending on altitude. It is also recommended to retest each infant to reduce the number of false-positives (W. T. Mahle et al., 2012). Any reading below 90% Oxygen Saturation should receive immediate evaluation, and an echocardiogram should be used to exclude CCHD (W. T. Mahle et al., 2012).

Before the recommendation from the U.S. Secretary of Health and Human Services, there was hesitation to recommend this screening due to the wide range of reported sensitivities (W. Mahle & Koppel, 2011). Based on a meta-analysis of a compilation of studies, the specificity remains consistent at approximately 99.9%, but the range for sensitivity spans from 60-87.5% (Zuppa et al., 2015). Specifically, Oster, Colarusso, and Glidewell (2013) esimated that roughly one child will receive a result that is a false positive for every three children with a true positve result, for a sensitivity of 76.5%. Despite this fairly low sensitivity level, pulse oximetry is still recommended because it is a relatively inexpensive, non-invasive procedure that hospitals can easily incorporate into current practices (Peterson, Grosse, et al., 2014; Peterson, Grosse, Oster, Olney, & Cassell, 2013; Pflugeisen et al., 2015; W. T. Mahle et al., 2009).

Additionally, the value of finding true positives before discharge has enormous economic as well as quality of life benefits. Ailes, Gilboa, Honein, and Oster (2015) estimate that the implementation of universal CCHD screening across the United States could detect 900 infants each year who would have otherwise been missed. The majority of these infants have conditions that would not be traditionally detected through a prenatal ultrasound or other clinical detection at birth (Ailes, Gilboa, Honein, & Oster,

2015). Based on a national survey from 1998-2007, an estimated one-third of live-born infants with nonsyndromic CCHD at birth received a delayed diagnosis (Peterson, Ailes, et al., 2014). Data from the Florida Birth Defects Registry from the same time period revealed that late CCHD diagnoses are associated with 52% more hospital admissions, 18% more days in the hospital and 35% higher inpatient costs during infancy as compared to those with CCHDs that were detected in a timely manner (Peterson, Dawson, et al., 2013).These infants have the most to beneft from routine CCHD screening to improve developmental outcomes.

The majority of quality of assurance measures and evaluation programs for CCHD screenings across the United States focus on improving the sensitivity and specificity for pulse oximetry (Pflugeisen et al., 2015). Ryan, Mikula, Germana, Silva, and Derouin (2014) evaluated the effectiveness of an online education module for training nurses on CCHD screening. Nurses who were trained on the significance and rational for implementation of CCHD screening had increased knowledge and adherence to CCHD screening protocols (Ryan, Mikula, Germana, Silva, & Derouin, 2014). Andrea (2015) evaluated the limitations surrounding the regulations imposed by different states. Few states have protocols in place for infants delivered in-home, which results in this population having a higher rate of missed diagnoses (Andrea, 2015). Specifically, the Wisconsin Department of Health Services included a mandate for screening infants born outside of the hospital setting; when implementing this mandate, a collaborative intervention was developed by the State of Wisconsin, the University of Wisconsin School of Medicine and Public Health and the Medical College of Wisconsin (Andrea, 2015). This intervention recommends the education of health care providers,

improvements to access for screenng and diagnostic technology and a statewide data collection system (Andrea, 2015).

Iyengar, Kumar, and Kumar (2014) evaluated the state-wide mandates to determine if any have regulations in place for the screening of children discharged from the neonatal intensive care unit (NICU). Based on the risk of these children, many receive pulse oximetry monitoring; however, approximately 5% of the infants who were discharged from the NICU go home without having had a pulse oximeter reading or leave with oxygen levels less than 95% (Iyengar, Kumar, & Kumar, 2014).

PRECEDE-PROCEED Model

The PPM is a widely accepted intervention planning and evaluating model. However, the model has seldom been used for medical or hospital-specific interventions. Previous studies utilizing PPM focus either on the PRECEDE phases to inform intervention development or utilize the whole model to report on the development, implementation and evaluation of an intervention. One reason for the scarcity of reported applications of this model is its recognized high cost. Following the entire process requires a lot of time, money and personnel (Gielen, McDonald, Gary & Bone, 2008).

Studies that specifically utilize PRECEDE phases focus on the assessment of the behavioral, environmental, educational and ecological factors; specifically, most assess the factors that predispose, reinforce or enable (Commodore-Mensah et al., 2015; Hanson, Wagner, Monopoli, & Keysor, 2007; Leonard et al., 2012). Knowledge of these contextual factors has helped to inform the development of a wide-range of interventions, such as: oral health interventions for adults with intellectual and developmental disabilities, interventions to improve sleep quality after undergoing coronary artery

bypass graft surgery, education interventions for oral anticoagulation therapy and interventions to introduce alcohol based hand rub in hospital and clinics (Binkley & Johnson, 2013; Ranjbaran, Dehdari, Sadeghniiat-Haghighi, & Majdabadi, 2015; Shaha et al., 2015; Sharma, Joshi, Shah, Macaden, & Lundborg, 2015). However, as previously discussed, PPM is more than a planning and intervention-development model.

Studies that have used PPM in its entirety have focused on various topics, including: a prevention training program for nursing assistants in long term care facilities; a plan for medical staff to improve swallowing, feeding, and oral care practices in orphanages; and an erectile dysfunction intervention (Bonner, MacCulloch, Gardner, & Chase, 2007; Colodny, Miller, & Faralli, 2015; Pournaghash-Tehrani & Etemadi, 2014). Overall hospital development and community integration has been assessed, implemented and evaluated across the globe (Delobelle, Onya, Langa, Mashamba, & Depoorter, 2010; Irimu et al., 2014; Lengerich et al., 2007). Chen, Yamada, Smith, and Chiu (2011) utilized PPM to analyze healthcare utilization behavior of children receiving Medicaid to best adapt the program and address the needs of this population.

Though PPM has not been previously used as an evaluation model for newborn screening, its use in previous studies suggest that it would be a good model for this type of program evaluation. This project will expand the PPM literature by evaluating the implementation process for the CCHD screening in Georgia through process and impact phases. This study can serve as a framework for future CCHD screening program evaluations. Results and recommendations from this project can be used to best implement CCHD screening for states that have not yet implemented regulations or could help guide states to best assist hospitals struggling with implementation.

Chapter III Methodology

Research Design

This study utilizes quantitative methods of data collection and analysis. Data were collected in this project by a survey of hospital administrators' experiences of and attitudes towards implementing the NBS Card. Data were also obtained through the active surveillance system for newborn screening results through the GA DPH, Maternal and Child Health Section. Results from the right and left ear hearing test and the CCHD screening are actively reported by hospitals to the GA DPH. This information was used to study trends in reporting over the time the NBS Card was introduced and the impact of hospital level on reports of screening results.

Ethics/Protection of Participants

A member of the research team submitted the research protocol to the Emory IRB to request a determination of whether this study constitutes "human subjects research" or "clinical investigation" according to the IRB definitions. The IRB determined that the nature of this project did not meet the criteria for human subjects research or clinical investigation, and therefore does not need IRB approval (see Appendix C). The IRB from the GA DPH chose to rely on the determination from the Emory IRB.

Impact on Prevalence

Data Collection and Management

The GA DPH receives daily, or occasionally weekly, updates from labor and delivery services with the results of the newborn screening. Data analyzed for this study consisted of six months (May 01, 2014 to October 31, 2014) before changes in the NBS Card reporting data and six months after these mandated changes (February 01, 2015 to

July 31, 2015), encompassing 121,657 total births. Data from November 01, 2014 to January 31, 2015 were not included due to the transitioning between reporting systems. During the first time period, hospitals may have routinely conducted hearing and CCHD screens, but were not required to report the results to the GA DPH. By the beginning of the second time period, all hospitals should have routinely reported the results of each screening to the GA DPH. The research team received de-identified data for the purposes of analyses. Data were linked to hospital information by the DPH. All data were stored on a password-protected laptop and were only accessed by members of the research team.

Variables of interest included: UNSAT, NICU, RIGHT, LEFT, CCHD, HOSPLEVEL, and SURVEY. The variable "UNSAT" refers to whether or not the NBS Card that was submitted to the GA DPH was deemed "satisfactory." The GA DPH staff member who enters in the data from the NBS Card determines whether or not a card is "satisfactory." The most common reasons for "unsatisfactory" submissions include: invalid or illegible demographic information, delayed reporting and problems with the saturation levels of the blood samples for the metabolic disease screenings, such as oversaturation, undersaturation or uneven saturation. "Unsatisfactory" card submission does not influence the reports of the other outcomes of interest. "NICU" is a dichotomous variable that identifies whether the NBS Card submission came from a Special Care Unit (Level II) or NICU (Level III) rather than from the regular labor and delivery unit (from here on out referred to as "regular unit"). The variables "Right" and "Left" refer to the results of the right and left ear hearing tests. Each reported birth was classified as either "pass," "refer," or "not reported." The variable "CCHD" refers to the results of the pulse oximetry test for CCHD. Each reported birth was classified as either "pass," meaning a

negative screen, “fail,” meaning a positive screen, or “not reported.” The variable “HOSPLEVEL” identifies the overall newborn unit classification for the hospital submitting the NBS Card. The variable “SURVEY” was created based on whether the hospital completed the developed survey.

Data Analysis

This study analyzed data using SAS 9.3 statistical software. Univariate statistics are used to describe distributions of unsatisfactory NBS Card submissions, NICU submissions, right and left ear hearing loss referrals, and results of the CCHD screenings for before and after the implementation period. Chi-square tests of independence were performed to examine the association between NICU and regular unit reports and the satisfactory NBS Card submissions as well as the reported results of each of the screenings, right and left ear hearing loss and CCHD. Chi-square tests of independence were then performed again for each of these associations stratified by the level of nursery. A logistic regression model was then conducted with hospital level and reports from a NICU.

Provider Perceptions

Participants

In December 2015, DPH distributed a survey about current CCHD screening practices and implementation to nurse managers at all the 78 Georgia birthing hospitals. Hospitals could complete the survey online, via fax, or by telephone. The only criterion for eligibility for a hospital to complete the survey was that the hospital provides Labor and Delivery services. By the end of the data collection period, 49 hospitals responded to the survey resulting in a 62.8% response rate.

Data Collection and Management

A representative from the GA DPH sent out emails with the survey link to labor and delivery nurse managers. Hospitals were reminded three times to complete the survey via email. Reminder emails were delivered once a week for the first three weeks of data collection. If completion had not occurred after the third reminder, a representative from DPH called the nurse manager to determine if the hospital preferred to complete the survey via telephone. During the phone conversations, a member of the research team concurrently entered survey responses into the spreadsheet as they were answered.

The survey addressed general hospital demographic information, such as number of delivery beds and type of newborn care unit, as well as the provider's perceptions on newborn screening and the utility of the NBS Card (see Appendix D). In regards to the hospitals' perceptions on the implementation of the Uniform Newborn Screening Specimen card, hospitals were asked a series of questions such as "do you feel the newborn screening improves the time to intervention for CCHD and hearing problems?" To address the hospital process of completing the NBS Card, hospitals were asked a series of questions, including "how would you describe the process for screening newborns in your hospital?"

Data Analysis

After completion of all online surveys and phone interviews, responses were verified for completion and the second entry of any duplicates were deleted. Data was stored using Microsoft Excel on a password protected computer. Responses were then analyzed using SAS 9.3 software. Overall univariate statistics were used to describe the distribution of each question across responding hospitals. Survey completion by hospital

was noted for birth data to determine how representative the hospitals that completed the survey are compared to those that did not complete the survey.

Chapter 4 Results

Impact on Prevalence

All reported births in Georgia between May 01, 2014 and October 31, 2014 (n=62,052), as well as February 01, 2015 and July 31, 2015 (n=59,605) were analyzed. Distributions of the pertinent information gathered from the NBS Cards for these time periods are presented in Table 1. Recorded births between November 01, 2014 and January 31, 2015 are not included in analysis due to the changes in the GA law on what should be reported for newborn screening. Very few test results were reporting before 2015 (Table 1). Therefore, analyses were conducted only for the results of the right and left ear hearing and CCHD tests for births that occurred between February 01, 2015 and July 31, 2015.

There is a statistically significant association between submission unit and unsatisfactory NBS cards for 2014 ($\chi^2 = 279.7$, $p<0.001$); more NBS cards were considered "unsatisfactory" from NICU submissions (n=386, 6.5%) in 2014 than those submitted from a regular newborn unit (n=1,537, 2.7%). Likewise, for 2015 more NBS cards were considered "unsatisfactory" from NICU submissions (n=285, 4.7%) than those submitted from a regular unit (n=1,350, 2.5%; $\chi^2 = 93.5$, $p<0.001$).

NICUs were also less likely to submit hearing tests for patients than were regular newborn units (Table 2; Right ear hearing test: $\chi^2 = 4,886.4$, $p<0.001$; Left ear hearing test: $\chi^2 = 4,852.4$, $p<0.001$). CCHD screening was also less common in NICUs as compared to regular newborn units (CCHD screening: $\chi^2 = 4,580.2$, $p<0.001$).

Based on these results, the rate of children who were screened in a NICU and reported being referred for right ear hearing loss is 51.9 per 1,000 infants compared to

41.0 per 1,000 infants who were screened in a regular newborn unit. If these rates reflect all infants admitted to these units, the expected number of infants from the NICU to be referred for right ear hearing loss would be 317, while, 2,190 infants from the regular unit would have been referred. This would mean that 18.9% of the infants expected to be referred for right ear hearing loss from the NICU and 65.1% of the expected infants from the regular units were found.

A similar relationship is shown for left ear hearing loss. The rate of referrals for NICU reports is 55.7 per 1,000 infants compared to 43.8 per 1,000 infants who were screened in a regular newborn unit. Based on these rates, the expected number of infants to be referred for left ear hearing loss from the NICU reports would be 340 and from the regular newborn unit reports would be 2,340. This would mean that 18.5% of the infants expected to be referred for left ear hearing loss from the NICU and 64.5% of the expected infants from the regular newborn units were found.

For infants who were screened for CCHD, the rate of positive screens from the NICU reports is 6.7 per 1,000 infants compared to 1.0 per 1,000 for infants in regular newborn units. Based on this rate, there would be 41 expected infants with positive CCHD screenings from the NICU and 53 infants from regular newborn units. This would mean that 19.5% of infants expected to screen positive for CCHD from the NICU and 64.2% of the expected infants from the regular newborn units were found.

There is a statistically significant association between level of hospital submitting the NBS card and reporting the results of each screening to the GA DPH (see Tables 3 through 5). For right and left ear screenings, hospitals with level I nurseries had higher rates of reporting the results to the GA DPH than hospitals with level II nurseries. For

CCHD screening, hospitals with level I nurseries had similar rates of reporting the results to the GA DPH to hospitals with level II nurseries. For each screenings though, hospitals with level I or II nurseries had higher rates of reporting the results to the GA DPH than hospitals with level III nurseries.

Level III hospitals, regardless of NICU or regular unit submission, had higher rates of not reporting the results for each test compared to level I or II hospitals (Tables 6-8). NICU submissions, whether from a level II or level III hospital, had the lowest rates of reporting results of each screening. Results from the logistic regression models are presented in Table 9 and 10.

The odds of a newborn unit from a Level 1 hospital reporting the results of the right ear hearing test is 15.1 times greater the reporting from a NICU from a Level 3 hospital (OR = 15.1, 95% CI = 13.7 – 16.8). The odds of a regular unit from a Level 2 hospital reporting the results of the right ear hearing test is 8.6 times than of reporting from a NICU from a Level 2 hospital (OR = 8.6, 95% CI = 7.7 – 9.6). The odds of a NICU from a Level 2 hospital reporting the results of the right ear hearing test is 1.4 times greater than of reporting from a NICU from a Level 3 hospital (OR = 1.4, 95% CI = 1.2 – 1.6). The odds of a regular unit from a Level 3 hospital reporting the results of the right ear hearing test is 7.1 times greater than that of reporting from a NICU from a Level 3 hospital (OR = 7.1, 95% CI = 6.5 – 7.7).

The odds of a newborn unit from a Level 1 hospital reporting the results of the left ear hearing test is 15.1 times that of reporting from a NICU from a Level 3 hospital (OR = 15.1, 95% CI = 13.6 – 16.7). The odds of a regular unit from a Level 2 hospital reporting the results of the left ear hearing test is 8.5 times that of reporting from a NICU

from a Level 2 hospital (OR = 8.5, 95% CI = 7.6 – 9.5). The odds of a NICU from a Level 2 hospital reporting the results of the left ear hearing test is 1.4 times that of reporting from a NICU from a Level 3 hospital (OR = 1.4, 95% CI = 1.2 – 1.6). The odds of a regular unit from a Level 3 hospital reporting the results of the left ear hearing test is 7.1 times that of reporting from a NICU from a Level 3 hospital (OR = 7.1, 95% CI = 6.5 – 7.7).

The odds of a newborn unit from a Level 1 hospital reporting the results of the CCHD screening is 12.4 times that of reporting from a NICU from a Level 3 hospital (OR = 12.4, 95% CI = 11.2 – 13.7). The odds of a regular unit from a Level 2 hospital reporting the results of the CCHD screening is 8.5 times that of reporting from a NICU from a Level 2 hospital (OR = 8.5, 95% CI = 7.6 – 9.4). The odds of a NICU from a Level 2 hospital reporting the results of the CCHD screening is 1.9 times that of reporting from a NICU from a Level 3 hospital (OR = 1.9, 95% CI = 1.6 – 2.1). The odds of a regular unit from a Level 3 hospital reporting the results of the CCHD screening is 7.0 times that of reporting from a NICU from a Level 3 hospital (OR = 7.0, 95% CI = 6.4 – 7.7).

Provider Perceptions

The hospitals that responded to the survey account for approximately 60% of the reported births that occurred in Georgia during the time periods of interest (May 01, 2014 to October 31, 2014: 36,303, 58.5%; February 01, 2015 to July 31, 2015: 35,152, 59.0%). The outcomes of interest for hospital performance based on hospitals that responded to the survey are presented in Table 11. Hospitals that responded perform similarly to

hospitals that did not respond to the survey, indicating that the results from the survey may be generalized to all hospitals in Georgia.

Table 12 presents the distribution of nursery level and average number of labor and delivery beds for the hospitals that responded to the survey. The majority of respondents (n=44, 89.8%) indicated that the hospital began routine screening for CCHD more than nine months ago (see Table 13). Of the hospitals that began screening more than nine months ago, the majority of hospitals (n=40, 90.9%) indicated that one of the reasons to initiate screening was because they believed that CCHD screening was the new standard of care. During the implementation of CCHD screening, approximately two-thirds of the respondents (n=32, 65.3%) reported that they experienced no barriers. Of the respondents that reported barriers, the most common barrier was the need to purchase new equipment in order to carry out the screenings (n=12, 70.6%).

Nurse managers then completed a series of questions on their perceptions of newborn screening and reporting the results on the NBS Card (see Table 14). The majority of providers believe that the NBS Card does not take time away from providing the best care to newborns (n=38, 82.6%) and is easy to complete (n=37, 80.5%). However, over half of the providers indicated that reporting the results on the NBS Card does not have an impact on providing the best care to the newborns (n=27, 58.7%). The majority of providers did indicate that newborn screening improves the time to intervention for medical conditions (n=42, 87.5%) and that the newborns' parents perceive these screenings as beneficial to their newborn's health (n=44, 89.8%).

The next series of questions related to the process by which the hospital staff performs the screens and reports the results to the GA DPH (see Table 15). Over half of

the hospitals decided to have different individuals perform each type of test (n=29, 59.2%). Of the hospitals that reported “other method” for the process for conducting newborn screening, their responses can be classified into the other two categories. Individual responses to explain this process are given in Appendix E. The majority of hospitals report the results of the screenings using the NBS card or a combination of the NBS Card and Delayed Screening Report Form (n=21, 42.9%; n=17, 34.7%). Of the two hospitals that indicated that they do not report the results of the new born screening, one did not comment as to why and the other indicated the hospital’s procedure for reporting results to the physicians and the follow-up process rather than the process for reporting the results to the DPH.

Table 1: Birth data recorded from the reported NBS Cards

May 01, 2014 – October 31, 2014	N=62,052
Reported from NICU*	5,970 (9.6%)
Reported from Regular Unit	56,016 (90.4%)
Satisfactory submission of the NBS Card	60,126 (96.9%)
Unsatisfactory submission of the NBS Card	1,926 (3.1%)
Results of right ear hearing test	
Negative	43 (0.1%)
Not given	62,009 (99.9%)
Results of left ear hearing test	
Negative	42 (0.1%)
Not given	62,010 (99.9%)
Results of CCHD screening	
Negative	40 (0.1%)
Not given	62,012 (99.9%)
February 01, 2015 – July 31, 2015	**N = 59,605**
Level 1 Nursery	5,603 (9.4%)
Level 2 Nursery	21,106 (35.4%)
Level 3 Nursery	32,896 (55.2%)
Reported from NICU*	6,115 (10.3%)
Reported from Regular Unit	53,417 (89.6%)
Satisfactory submission of the NBS Card	57,968 (97.3%)
Unsatisfactory submission of the NBS Card	1,637 (2.7%)
Results of the right ear hearing test	
Negative	34,456 (57.8%)
Referred	1,487 (2.5%)
Not Given	23,662 (39.7%)
Results of the left ear hearing test	
Negative	34,236 (57.4%)
Referred	1,582 (2.7%)
Not Given	23,787 (39.9%)
Results of the CCHD screening	
Negative	35,533 (59.6%)
Positive	42 (0.1%)
Not Given	24,030 (40.3%)

*One submitted card (0.0%) from the first period of births and 73 submitted cards (0.1%) from the second period did not report whether the NBS Card was reported from a NICU or regular unit.

Table 2: Birth data by submission from a NICU

May 01, 2014 – October 31, 2014	NICU	Regular Unit
Satisfactory NBS Card	5,584 (93.5%)*	54,479 (97.3%)*
Unsatisfactory NBS Card	386 (6.5%)*	1,537 (2.7%)*
February 01, 2015 – July 31, 2015		
Satisfactory NBS Card	5,830 (95.3%)*	52,067 (97.5%)*
Unsatisfactory NBS Card	285 (4.7%)*	1,350 (2.5%)*
Results of right ear hearing test		
Negative	1,095 (17.9%)*	33,323 (62.4%)*
Positive	60 (1.0%)*	1,425 (2.7%)*
Not given	4,960 (81.1%)*	18,669 (35.0%)*
Results of left ear hearing test		
Negative	1,086 (17.8%)*	33,112 (62.0%)*
Positive	63 (1.0%)*	1,518 (2.8%)*
Not given	4,944 (81.2%)*	18,787 (35.2%)*
Results of CCHD screening		
Negative	1,187 (19.4%)*	34,309 (64.2%)*
Positive	8 (0.1%)*	34 (0.1%)*
Not given	4,920 (80.5%)*	19,074 (35.7%)*

* $p<0.001$

Table 3: Results from right ear hearing test reported to GA DPH by hospital level

Hospital Level	Results Reported	Results Not Reported
Level I	4,184 (74.7%)	1,419 (25.3%)
Level II	13,947 (66.1%)	7,159 (33.9%)
Level III	17,812 (54.2%)	15,084 (45.9%)

* χ^2value = 1,298.6, $p<0.001$

Table 4: Results from left ear hearing test reported to GA DPH by hospital level

Hospital Level	Results Reported	Results Not Reported
Level I	4,173 (74.5%)	1,430 (25.5%)
Level II	13,896 (65.8%)	7,210 (34.2%)
Level III	17,749 (54.0%)	15,147 (46.0%)

* χ^2value = 1,290.9, $p<0.001$

Table 5: Results from CCHD test reported to GA DPH by hospital level

Hospital Level	Results Reported	Results Not Reported
Level I	3,873 (69.1%)	1,730 (30.9%)
Level II	14,763 (70.0%)	6,343 (30.0%)
Level III	16,939 (51.5%)	15,957 (48.5%)

* χ^2 value = 2,048.7, $p<0.001$

Table 6: Results from right ear hearing test reported to GA DPH by submission unit and hospital level

	Results Reported	Results Not Reported
Regular Unit Submission from Level I Hospital**	4,145 (75.6%)	1,335 (24.4%)
Regular Unit Submission from Level II Hospital	13,489 (70.7%)	5,582 (29.3%)
Regular Unit Submission from Level III Hospital	17,114 (59.3%)	11,752 (40.7%)
NICU Submission from Level II Hospital	442 (22.0%)	1,567 (78.0%)
NICU Submission from Level III Hospital	679 (17.0%)	3,311 (83.0%)

* χ^2 value = 5,774.3, $p<0.001$
**189 card submissions were excluded since they indicated NICU submission from a level I hospital

Table 7: Results from left ear hearing test reported to GA DPH by submission unit and hospital level

	Results Reported	Results Not Reported
Regular Unit Submission from Level I Hospital**	4,135 (75.4%)	1,346 (24.6%)
Regular Unit Submission from Level II Hospital	13,440 (70.5%)	5,631 (29.5%)
Regular Unit Submission from Level III Hospital	17,056 (59.1%)	11,810 (40.9%)
NICU Submission from Level II Hospital	440 (21.9%)	1,569 (78.1%)
NICU Submission from Level III Hospital	675 (16.9%)	3,315 (83.1%)

* χ^2 value = 5,733.8, $p<0.001$
**189 card submissions were excluded since they indicated NICU submission from a level I hospital

Table 8: Results from CCHD screening reported to GA DPH by submission unit and hospital level

	Results Reported	Results Not Reported
Regular Unit Submission from Level I Hospital**	3,815 (69.6%)	1,665 (30.4%)
Regular Unit Submission from Level II Hospital	14,231 (74.6%)	4,840 (25.4%)
Regular Unit Submission from Level III Hospital	16,297 (56.5%)	12,569 (43.5%)
NICU Submission from Level II Hospital	518 (25.8%)	1,491 (74.2%)
NICU Submission from Level III Hospital	623 (15.6%)	3,367 (84.4%)

* χ^2 value = 5,733.8, $p<0.001$
**189 card submissions were excluded since they indicated NICU submission from a level I hospital

Table 9: Odds of reporting results of each screening by submission unit and hospital level as compared to NICU submission from level III hospitals

	Odds Ratio	95% Confidence Interval
Results of right ear hearing test reported to GA DPH		
Regular Unit Submission from Level I Hospital	15.1	13.7 – 16.8
Regular Unit Submission from Level II Hospital	11.8	10.8 – 12.9
Regular Unit Submission from Level III Hospital	1.4	1.2 – 1.6
NICU Submission from Level II Hospital	7.1	6.5 – 7.7
NICU Submission from Level III Hospital	(Ref)	-
Results of left ear hearing test reported to GA DPH		
Regular Unit Submission from Level I Hospital	15.1	13.6 – 16.7
Regular Unit Submission from Level II Hospital	11.7	10.7 – 12.8
Regular Unit Submission from Level III Hospital	1.4	1.2 – 1.6
NICU Submission from Level II Hospital	7.1	6.5 – 7.7
NICU Submission from Level III Hospital	(Ref)	-
Results of CCHD screening reported to GA DPH		
Regular Unit Submission from Level I Hospital	12.4	11.2 – 13.7
Regular Unit Submission from Level II Hospital	15.9	14.5 – 17.4
Regular Unit Submission from Level III Hospital	1.9	1.6 – 2.1
NICU Submission from Level II Hospital	7.0	6.4 – 7.7
NICU Submission from Level III Hospital	(Ref)	-

Table 10: Odds of reporting results of each screening by submission unit and hospital level as compared to NICU submission from level II hospitals

	Odds Ratio	95% Confidence Interval
Results of right ear hearing test reported to GA DPH		
Regular Unit Submission from Level I Hospital	11.0	9.7 – 12.4
Regular Unit Submission from Level II Hospital	8.6	7.7 – 9.6
Regular Unit Submission from Level III Hospital	5.2	4.6 – 5.8
NICU Submission from Level II Hospital	(Ref)	-
NICU Submission from Level III Hospital	0.7	0.6 – 0.8
Results of left ear hearing test reported to GA DPH		
Regular Unit Submission from Level I Hospital	11.0	9.7 – 12.4
Regular Unit Submission from Level II Hospital	8.5	7.6 – 9.5
Regular Unit Submission from Level III Hospital	5.2	4.6 – 5.7
NICU Submission from Level II Hospital	(Ref)	-
NICU Submission from Level III Hospital	0.7	0.6 – 0.8
Results of CCHD screening reported to GA DPH		
Regular Unit Submission from Level I Hospital	6.6	5.9 – 7.4
Regular Unit Submission from Level II Hospital	8.5	7.6 – 9.4
Regular Unit Submission from Level III Hospital	3.7	3.4 – 4.1
NICU Submission from Level II Hospital	(Ref)	-
NICU Submission from Level III Hospital	0.5	0.5 – 0.6

Table 11: Hospital performance measures by response to the DPH survey on provider perceptions

	Respondents	Non-respondents
2014 Unsatisfactory	960 (1.6%)	966 (1.6%)
2015 Unsatisfactory	746 (1.3%)	891 (1.5%)
Right Ear Hearing Test Reports	21,065 (59.9%)	14,878 (60.8%)
Left Ear Hearing Test Reports	20,980 (59.7%)	14,838 (60.7%)
CCHD Screen Reports	21,607 (61.5%)	13,968 (57.1%)

Table 12: Hospitals that Responded to Survey Demographic Information

Total Hospital Responses	N = 49
Well-Baby/Newborn (Level I) Nursery	18 (36.7%)
Special Care (Level II) Nursery	14 (28.6%)
Neonatal Intensive Care Unit (Level III) Nursery	17 (34.7%)
Labor and Delivery Beds	10.3 (sd = 10.6)
Well-Baby/Newborn (Level I) Nursery	5.2 (sd = 3.4)
Special Care (Level II) Nursery	9.9 (sd = 5.6)
Neonatal Intensive Care Unit (Level III) Nursery	15.4 (sd = 15.0)

*Reported as N and Percent or Mean and Standard Deviation

Table 13: Information on the Initiation of Screening for CCHD

Initiation of routine screening for CCHD	N (%)
Less than 3 months ago	0 (0.0%)
3 to 6 months ago	1 (2.0%)
6 to 9 months ago	4 (8.2%)
More than 9 months ago	44 (89.8%)
Top reasons to initiate CCHD Screening*	
Believed that CCHD screening was the new standard of care	40 (90.9%)
Concerned about missing an infant with CCHD	18 (41.9%)
Required by the hospital's health system	13 (29.6%)
Believed that it is cost effective medicine	11 (25.0%)
Top barriers experienced during implementation of CCHD Screening	
No barriers	32 (65.3%)
Need to purchase new equipment**	12 (70.6%)
Unsure on how to report results**	7 (41.2%)
Concerned about reimbursement for cost of screening**	5 (29.4%)
No clear plan for follow-up of positive results**	3 (17.6%)
Believed that number of false positives would be too high**	1 (5.9%)

*Only for the 44 hospitals that indicated screening for CCHD started over 9 months ago
**Percentages are out of 17 hospitals that reported experiencing any barriers

Table 14: Provider Perceptions to NBS Card and Newborn Screening

NBS Card takes time away from providing the best care*	N(%)
Yes	8 (17.4%)
No	38 (82.6%)
NBS Card has an impact on providing the best care*	
Yes	19 (41.3%)
No	27 (58.7%)
NBS Card is confusing to complete*	
Yes	9 (19.5%)
No	37 (80.5%)
Newborn screening improves time to intervention	
Yes	42 (87.5%)
No	6 (12.5%)
The newborn's parents perceive newborn screening as beneficial	
Yes	44 (89.8%)
No	5 (10.2%)

*46 hospitals utilize the NBS Card to report results of newborn screening

Table 15: Hospital Process for Conducting Newborn Screening and Reporting Results

Process for conducting newborn screening	N(%)
Different individuals perform each test	29 (59.2%)
One individual performs all screens	2 (4.1%)
Other method	18 (36.7%)
Reporting mechanism	
NBS Card	21 (42.9%)
Delayed Screening Report Form	1 (2.0%)
Both (NBS Card and Delayed Screening Report Form)	17 (34.7%)
Don't report	2 (4.1%)
Other mechanism	8 (16.3%)

* Reported as N and Percent

Chapter 5 Discussion

Introduction

Since the U.S. Secretary of Health and Human Services recommended universal CCHD screening many states have adopted some standard protocol for using pulse oximetry during newborn screening procedures. Starting January 2015 Georgia implemented routine CCHD and hearing screenings for all labor and delivery hospitals. The current study evaluated the impact and the process of these screenings by use of phases six and seven of the PPM. To evaluate the impact, analyses on data from Georgia's active surveillance system for Newborn Screening Results were conducted. For the process evaluation, nurse managers from Georgia Labor and Delivery hospitals completed a survey on their perceptions of and process for completing newborn screening and reporting the results.

Positioning Findings in Theoretical Context

Impact Evaluation (Phase 7)

Research Question 1: Is the level of newborn unit providing the NBS Card associated with the proportion of unsatisfactory NBS card submissions?

The proportion of unsatisfactory card submissions did not vary between the two time periods. However, there were a higher proportion of unsatisfactory NBS card submissions from NICUs as compared to cards submitted from a regular unit. Since a card that is deemed as "unsatisfactory" means that the quality of the data being reported is compromised in some way, such as problems with the bloodspot or illegible demographic information, this difference could be due to the differing natures between a NICU and a regular unit. This is to say, that the staff in a NICU work in a more chaotic

atmosphere may not devote the same amount of time to completing the NBS Card to "satisfactory" standards.

Research Question 2: Is the implementation of the NBS Card associated with reported prevalence of referrals for hearing loss in GA? Sub Question: Is the level of unit providing the results associated with reports of hearing loss screening?

Before January 2015, there were very few reports for the results of the right and left ear hearing tests, as expected, since hospitals did not have a system for reporting the results to the GA DPH. In the six months following implementation reports of the screening increased, but approximately 40% of the results of the right and left ear hearing tests were not reported. Specifically, hospital reports of the hearing test results decreased as the nursery level increased, with Level III hospitals having the poorest rates of reporting the results.

NBS Cards submitted by a NICU were less likely to contain the results of the right and left ear hearing tests as compared to cards submitted by a regular unit. The starkest difference is shown between a regular unit from a Level I hospital and a NICU from a Level III hospital, in which the regular unit is approximately 15 times more likely to report the results of the hearing tests than the NICU. In accordance with the Georgia code on newborn screening, if an infant is in the NICU for more than five days, hearing screening must "be conducted after 32 weeks gestational age and when the baby is medically stable, and must include an aABR" (Ga. Comp. R. & Regs. r. 511-5-5-.06). This clause indicates that the hearing tests may occur in the NICU but the results of the tests are not being reported to the GA DPH. Since the NBS Card is designed to submit

data on newborn screening that occurs at 24 hours after birth, hearing screening in a NICU, especially for preterm infants, may not occur within this time period.

Though NICUs have low reporting of the results of the hearing tests, when comparing NICUs from hospitals with Level II and Level III nursery, a NICU from a hospital with a Level II nursery is approximately 7 times more likely to report the results of the tests as compared to a NICU from a hospital with a Level III nursery. Moreover, within the hospitals with Level III nurseries the regular unit is more likely to report the results of the hearing tests as compared to the NICU, but only slightly. This may indicate issues with reporting that go beyond the submission unit and are more about overall hospital performance that varies by level of newborn unit.

Research Question 3: Is the implementation of the NBS Card associated with the reported prevalence of CCHD in GA? Sub Question: Is the level of unit providing the results associated with reports of CCHD screening?

As with the results of the hearing tests, before January 2015, there were very few reports for the results of the CCHD screening. Similar to the hearing tests this is to be expected since hospitals did not have a system for reporting the results to the GA DPH. In the six months following implementation reports of the screening increased, but approximately 40% of the results of the CCHD screening were still not reported. Specifically hospital reports of the CCHD screening results were similar for hospitals with Level I and II nurseries and those with Level III nurseries had the poorest rates of reporting the results.

NBS Cards submitted by a NICU were less likely to contain the results of the CCHD screening as compared to cards submitted by a regular unit. Similar to the hearing

screenings, the largest difference exists between a regular unit from a Level I hospital and a NICU from a Level III hospital; wherein the regular unit is approximately 12 times more likely to report the results of the hearing tests than the NICU. The Georgia code does have additional guidance for conducting CCHD screening for infants admitted to a NICU. This stipulation states: "If the baby is admitted into a NICU or SCN, the baby shall have a CCHD screening test prior to discharge or once the baby is weaned from supplemental oxygen. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening" (Ga. Comp. R. & Regs. r. 511-5-5-.05). This clause indicates that the CCHD screening may occur in the NICU, but the results of the tests are not being reported to the GA DPH since the primary method of data collection, the NBS Card, is designed to submit data on newborn screening that occurs at 24 hours after birth.

Though NICUs have low reporting of the results of the CCHD screening, a comparison of NICUs from hospitals with Level II and Level III nurseries shows that a NICU from a hospital with a Level II nursery is approximately 7 times more likely to report the results of the tests, as compared to a NICU from a hospital with a Level III nursery. Moreover, within the hospitals with Level III nurseries, the regular unit is only two times more likely to report the results of the hearing tests as compared to the NICU. This provides additional evidence that there may be issues with overall hospital performance that varies by level of newborn unit.

Process Evaluation (Phase 6)

Research Question 4: What do providers perceive in regards to the process and impact of newborn screening and reporting the results?

Since the hospitals that completed the survey had similar results on the outcomes of interest to the hospitals that did not respond to the survey, it may be possible to generalize the responses of this survey to the attitudes of all nurse managers in labor and delivery hospitals in Georgia. The majority of respondents indicated positive perceptions of newborn screening, with the majority saying that newborn screening improves the time to intervention and that the parents perceive the screenings as beneficial to their infant's health. In regards to reporting the results of the newborn screening tests, many of the providers indicated that the NBS Card is relatively easy to use and does not take time away from providing the best care to the patients. However, over half of the providers indicated that they did not feel completing the NBS Card has an impact on providing the best care. This indicates the differences on the perception of data for clinical practice and public health. The GA DPH can use this data to inform health policy and medical interventions at the state level, but the hospital staff may not see the added benefit to including additional procedures and forms into clinical practice.

Implications and Limitations

According to the rates determined by the number of infants that screened positive for hearing problems compared to the total number of infants with reported results, the expected number of infants from a NICU to be referred for right ear hearing loss would be 317, indicating that only about one in five of these infants were actually referred. In comparison, 2,190 infants from a regular unit would be referred for right ear hearing loss and about two-thirds of these infants were referred. Similar rates are observed for left ear hearing loss. Based on the rates for positive screen of CCHD, the expected number of infants to screen positive from a NICU would be 41, indicating that only about one in

five of these infants screened positive; whereas 53 infants were expected to screen positive from a regular unit. Approximately two-thirds of these infants screened positive for CCHD.

A limitation of the current study is that the rates were based on the reported results of hearing tests and CCHD screening to the GA DPH. It could be that the results of each test are more likely to be reported for infants in the NICU who show more severe signs of these problems, therefore inflating these numbers and suggesting a higher burden of disease than in actuality.

Based on the Iyengar et al. (2014) evaluation study of pulse oximetry screenings in a NICU, 5% of infants gets discharged from the unit without any pulse oximetry monitoring. The current study found that about 40% of infants' results of the CCHD screening are not reported. The previous study used chart abstraction to collect data on the procedures of CCHD screening and determine how many infants from a NICU had any pulse oximetry screening, if needed (Iyengar et al., 2014). The current study focused on records from the GA DPH. The difference in results from these studies may indicate that hospitals are conducting the screenings, but the results do not get reported to the GA DPH.

Another limitation for this study is the amount of human error that could influence the results. For instance, a nurse must complete the NBS Card by hand, then an employee from the GA DPH enters the data from the NBS Card into their database, and then the investigator completed the analysis and manipulated some of the variables. Evidence for potential human error is that some of the NBS Cards submitted by hospitals with a Level I nursery also had indicated the card was submitted by a NICU. Since the

NICU variable only applies to Level II and III nurseries, these cards could not have been submitted by a NICU. There was no way to know if the error was on the part of the person completing the card or the person entering the data into the database. However, this can influence the integrity of the rest of the data in the database.

Additional limitations for this study pertain to the survey. First, though the hospitals account for over half of the births in the state and the hospitals that responded had similar results to the outcomes of interest as compared to the hospitals that did not respond, the hospitals that responded could be systematically different from the hospitals that did not respond in some unmeasured way. This would influence the generalizability of the results of the survey across all Labor and Delivery hospitals in Georgia. Secondly, since the survey was sent through an employee of the GA DPH and asks questions about hospital procedures and their interaction with the GA DPH, social desirability bias may be a factor that influences the responses. Nurse managers may have answered the questions the way they thought the GA DPH would want them to respond.

Recommendations for Future Research

Future research projects should focus on determining the cause of the issues in reporting with hospitals that have Level III nurseries and NICUs, utilizing similar methodology employed in the Iyengar et al. (2014) article. Potential causes would be that the hospitals are completing the screenings but the results are not being reported to the GA DPH by means of the NBS Card, or the hospitals are not completing the screenings at all. One way to determine whether screenings were occurring or not would be a study that focused on abstracting medical records for NICUs and hospitals with Level III nurseries. The medical records would be randomly sampled based on the DPH data records of

infants that do not have reported data for the CCHD screening and hearing tests. Evidence that this would be an effective method for determining if screening occurs through the provider survey. Eight hospitals indicated that the hospital used another method for reporting results of the screenings. Most of these hospitals indicated a process of inputting the data into the electronic medical record, though an electronic submission system only pertains to three hospitals in Georgia. A future study should utilize this information to determine if hospitals are completing the screenings.

Based off the findings of this future study the GA DPH could develop two different approaches to address the issue. If hospitals with Level III nurseries and NICUs are not completing the screenings the GA DPH should develop materials to help better integrate the screenings into the hospitals' current newborn screening procedures. However, if the results of the proposed study indicate that the screenings are occurring, but the results are not being reported to the GA DPH, then alterations to the current reporting system should be taken into consideration. Alterations to the reporting system may be most effective for NICUs since the screenings may occur at a later time period than what is intended by the current NBS Card.

Conclusion

Since January 2015, Georgia has added mandated screening and reporting for hearing loss and CCHD to the newborn screening procedures. Utilizing the PPM the impact of this mandate has increased reporting for these conditions, but approximately 40% of submitted NBS Cards do not have results for these tests after the mandate. This number increases when investigating cards submitted by a NICU and hospitals with Level III nurseries. In evaluating the process for newborn screening and reporting the

results, the majority of hospitals indicating that method of reporting is not confusing and does not take time away from providing the best care, but the majority of hospitals indicated that reporting results does not have an impact on providing the best care. Future research should focus on determining if hospitals, especially within NICUs and hospitals with Level III nurseries, complete these tests and if there is an issue with reporting the results to the GA DPH. Increased screening and reporting of the results can identify the true burden of hearing loss and CCHD in Georgia.

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Ga. Comp. R. & Regs. r. 511-5-5-.01 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Definitions" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013. Repealed: New Rule entitled "Purpose" adopted. F. May 13, 2014; eff. Jun. 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.02 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Provisions" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013. Repealed: New Rule entitled "Definitions" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.03 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Testing Required of Newborn Babies" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.04 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Newborn Screening Specimen Cards and Laboratory Analysis" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.05 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Critical Congenital Heart Disease Screening" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.06 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Hearing Screening" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.07 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Approved Laboratories" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.08 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Abnormal Test Results" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.09 Authority: O.C.G.A. 31-12-2, 31-1-3.2 History. Original Rule entitled "Reporting" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Ga. Comp. R. & Regs. r. 511-5-5-.10 Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7. History. Original Rule entitled "Revisions to Newborn Screening Panel" adopted. F. May 13, 2014; eff. Jun 2, 2014.

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Appendix A

Subject 511-5-5 TESTING FOR INHERITED DISORDERS IN THE NEWBORN

Rule 511-5-5-.01 Purpose

The purpose of these rules is to provide administrative details and procedures to ensure that all newborn babies in Georgia are promptly tested for certain conditions which pose a threat of severe illness, physical or developmental disability, or death.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.01

Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

History. Original Rule entitled "Definitions" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013. Repealed: New Rule entitled "Purpose" adopted. F. May 13, 2014; eff. Jun. 2, 2014.

Rule 511-5-5-.02 Definitions

a) "Abnormal test result" is a test result from blood testing or physiologic monitoring that is outside the screening limits set forth in the current edition of the Department's "Georgia Newborn Screening Program Policy and Procedure Manual";
b) "Adequate specimen" is a dried blood spot specimen that is properly collected in accordance with the current edition of the Department's "Georgia Newborn Screening Program Policy and Procedure Manual";
c) "Approved laboratory" is a laboratory licensed in Georgia which has been specifically approved by the Department to conduct laboratory analysis of dried blood spot specimens for the disorders specified in the Georgia Newborn Screening Policy and Procedure Manual;
d) "Automated auditory brainstem response" or "aABR" is a specific test method that measures the brainstem's response to acoustic stimulation of the ear, using equipment that automatically provides a pass/refer outcome;
e) "Automated Otoacoustic Emissions Testing" or "aOAE" is a specific test method that elicits a physiologic response from the outer hair cells in the cochlea, using equipment that automatically provides a pass/refer outcome;
f) "Birthing center" means any facility that is licensed by the Georgia Department of Community Health as a birthing center;
g) "Critical Congenital Heart Disease" or CCHD refers to a group of serious heart defects that are present from birth, including coarctation of the aorta, double-outlet right ventricle, D-transposition of the great arteries, Ebstein anomaly, hypoplastic left heart syndrome, interrupted aortic arch, pulmonary atresia, single ventricle, total anomalous pulmonary venous connection, tetralogy of Fallot, tricuspid atresia, and truncus arteriosus;
h) "Department" means the Georgia Department of Public Health;
i) "Hospital" means any facility that is licensed by the Georgia Department of Community Health as a hospital;
j) "Newborn Screening Specimen Card" or "NBS Card" means the current version of DPH Form 3491 used to collect information and blood specimen from a newborn baby;
k) "Newborn Hearing Screening Test" means the completion of an objective, physiological test or battery of tests administered to determine the infant's hearing

status and the need for further diagnostic testing by an audiologist or physician in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual's approved instrumentation, protocols and pass/refer criteria;

l) "Newborn Screening and Genetics Advisory Committee (NBSAC)" is a multi-disciplinary group of professional and consumer representatives with knowledge and expertise in newborn screening programs appointed by the Commissioner of Public Health;
m) "Submitter" means any person or entity submitting a Newborn Screening Specimen Card for analysis;
n) "Unsatisfactory Specimen" is a dried blood spot specimen that is rejected by the laboratory because the quality of the specimen does not allow accurate testing, or because critical information is missing from the NBS Card which inhibits the laboratory's ability to accurately identify the baby or interpret the test results.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.02
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.
History. Original Rule entitled "Provisions" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013. Repealed: New Rule entitled "Definitions" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.03 Testing Required of Newborn Babies

1) It is the goal of the Department that every baby born alive in Georgia shall be tested for the following conditions, unless its parents or legal guardians object in writing on the ground that such tests and treatment conflict with their religious beliefs:
    a. critical congenital heart disease (CCHD),
    b. hearing impairment,
    c. argininosuccinic aciduria,
    d. beta-ketothiolase deficiency,
    e. biotinidase deficiency,
    f. carnitine uptake defect,
    g. citrullinemia,
    h. congenital adrenal hyperplasia,
    i. congenital hypothyroidism,
    j. cystic fibrosis,
    k. galactosemia,
    l. glutaric academia type I,
    m. homocystinuria,
    n. isovaleric academia,
    o. long-chain acyl-CoA dehydrogenase deficiency,
    p. maple syrup urine disease,
    q. medium-chain acyl Co-A dehydrogenase deficiency,
    r. methylmalonic academia,
    s. multiple carboxylase deficiency,
    t. phenylketonuria,
    u. propionic academia,

v. severe combined immunodeficiency,
w. sickle cell hemoglobinopathies,
x. trifunctional protein deficiency,
y. tyrosinemia,
z. very long-chain acyl-CoA dehydrogenase deficiency,
aa. 3-methylcrotonyl-CoA dcarboxylase deficiency, and
bb. 3-OH 3-CH3 glutaric aciduria

2) Unless otherwise noted in subparagraph (1) above, testing for conditions (1)(c) through (1)(bb) shall be conducted through laboratory analysis of the baby's blood on a Newborn Screening Specimen Card as provided in DPH Rule 511-5-5-.04.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.03
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.

History. Original Rule entitled "Testing Required of Newborn Babies" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.04 Newborn Screening Specimen Cards and Laboratory Analysis

1) It shall be the responsibility of the hospital, birthing center, physician's office or other healthcare facility in which the baby is born to ensure that a NBS Card is properly completed and submitted to the Department in accordance with these Rules, and that the parents are given a copy of DPH Form 5506 ("Georgia Newborn Screening Program: What Every Parent Should Know"). If the birth occurs outside a hospital, birthing center, or other healthcare facility, then it shall be the responsibility of the attending physician or midwife to do so.
2) A Newborn Screening Dried Bloodspot Specimen (DBS) shall be completed 24 hours after birth, as follows:
    a. All information requested on the NBS Card shall be legibly and accurately collected;
    b. Specimens of the baby's blood shall be collected and placed on the DBS in accordance with the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual, and allowed to dry for at least three hours;
    c. The NBS Card shall be sent within 24 hours to the Department's Public Health Laboratory, using a courier service that ensures next business day delivery and allows the tracking of the package. A copy of the completed NBS Card shall be maintained with the baby's clinical records;
    d. If a NBS Card does not reach the Public Health Laboratory within seven days after the blood sample was drawn, the submitter shall repeat this process and submit a new Card for that baby.
3) If the baby is admitted into a Neonatal Intensive Care Unit (NICU) or Special Care Nursery (SCN), the baby shall have up to three specimens collected in accordance with the current edition of the Georgia Newborn Screening Program Policy and Procedure Manual.

4) The Department shall charge a fee of $50.00 per baby, for screening, patient retrieval and diagnosis to meet or defray Department cost. However, no parent shall be denied screening on the basis of inability to pay.
5) If the Department or approved laboratory determines that the specimen is unsatisfactory, then the submitter shall obtain a second specimen and submit another Card as soon as possible, but before the baby reaches three to four weeks of age. If the baby has been discharged, then the submitter shall be responsible for contacting the baby's physician, healthcare provider, or parent or legal guardian to arrange for the second specimen.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.04
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.
History. Original Rule entitled "Newborn Screening Specimen Cards and Laboratory Analysis" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.05 Critical Congenital Heart Disease Screening

1) All hospitals and birthing centers shall be equipped to conduct a CCHD screening test on newborn babies in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual.
2) When a live birth occurs in any hospital, birthing center or in a facility that is equipped to conduct a CCHD screening test the test shall be conducted prior to the baby's discharge in accordance with the Georgia Newborn Screening Policy and Procedure Manual. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening.
3) If the baby is admitted into a NICU or SCN, the baby shall have a CCHD screening test prior to discharge or once the baby is weaned from supplemental oxygen. Newborns who have already received an echocardiogram for any reason may be excluded from CCHD screening.
4) The person administering the test shall ensure that the CCHD screening test is conducted in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual.
5) The results of the test shall be included in the baby's clinical record, reported to the Department, and given to the parents or legal guardians, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.05
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.
History. Original Rule entitled "Critical Congenital Heart Disease Screening" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.06 Hearing Screening

1) All hospitals and birthing centers shall be equipped to conduct a newborn hearing screening test in accordance with these Rules.
2) When a live birth occurs in a hospital or birthing center or in an office or facility that is equipped to conduct a newborn hearing screening test according to these

Rules, a newborn hearing screening test shall be conducted prior to the baby's discharge.

3) A newborn hearing screening test shall be conducted in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual as follows:
    a. If the baby is in the well-baby nursery, then the test shall be conducted by aOAE and/or aABR;
    b. If the baby is in a SCN or NICU, for greater than five days, then the test shall be conducted after 32 weeks gestational age and when the baby is medically stable, and must include an aABR;
    c. If the baby does not pass the initial newborn hearing screening test, then the submitter may perform a second newborn hearing screening test prior to hospital discharge in accordance with the Georgia Newborn Screening Program Policy and Procedure Manual;
    d. In the event that a baby is transferred to another hospital or birthing center before the newborn hearing screening test has been completed, then it is the responsibility of the second facility to assure that a newborn hearing screening test is completed.
4) The results of the test shall be included in the baby's clinical record, reported to the Department, and given to the parents or legal guardians along with any follow-up recommendations, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.06
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.
History. Original Rule entitled "Hearing Screening" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.07 Approved Laboratories

1) A private laboratory may seek approval from the Department to conduct newborn screening laboratory analysis by showing to the Department's satisfaction that it is licensed in Georgia, that it holds a valid Certificate of Accreditation or Certificate of Registration from CMS to perform high-complexity testing of newborns for the conditions listed in DPH Rule 511-5-5-.03(c) through (bb), and that it can perform consistent and reliable testing in accordance with the Rules of the Department.
2) Approved laboratories performing analysis of a Georgia Newborn Screening Specimen Card shall conduct testing for all of the conditions listed in DPH Rule 511-5-5-.03(c) through (bb), and shall report the results of the testing to the appropriate newborn screening follow-up provider and submitter on the day that testing is completed.
3) Approved laboratories shall retain the Cards according to the retention schedule in the current Georgia Newborn Screening Program Policy and Procedure Manual.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.07
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.
History. Original Rule entitled "Approved Laboratories" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.08 Abnormal Test Results

1) In the event of an abnormal test result from the NBS Card, the appropriate newborn screening follow-up provider shall notify the baby's physician or healthcare provider, and the parent or legal guardian, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.
2) In the event of an abnormal test result for CCHD, an appropriate assessment or referral shall be made immediately, in accordance with the Georgia Newborn Screening Policy and Procedure Manual.
3) In the event of a newborn not passing the newborn hearing screening test, the person administering the newborn hearing screening test shall notify the Department of Public Health (DPH) in accordance with the Georgia Newborn Screening Policy and Procedure Manual
4) If the parents or legal guardians cannot be reached or are non-responsive, the Department or the parents' county health department should be contacted for assistance.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.08
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.
History. Original Rule entitled "Abnormal Test Results" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.09 Reporting

Every licensed or permitted hospital, laboratory and physician confirming abnormal test results or clinical symptoms for the conditions listed in DPH Rule 511-5-5-.03 must report those findings to the appropriate follow-up provider and to the Department in accordance with the Georgia Newborn Screening Policy and Procedure Manual.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.09
Authority: O.C.G.A. 31-12-2, 31-1-3.2
History. Original Rule entitled "Reporting" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Rule 511-5-5-.10 Revisions to Newborn Screening Panel

The Commissioner of Public Health may from time to time change the roster of conditions for which testing is required. In determining which conditions are to be added or deleted from the newborn screening panel, the Commissioner may seek the advice and guidance of the Newborn Screening and Genetics Advisory Committee. Criteria to be considered in adding disorders shall include, without limitation, the following:

a) Whether the disorder has significant morbidity and mortality when not identified and not treated before symptoms appear;
b) Whether early clinical identification of the disorder is unlikely;
c) Whether the prevalence of the disorder in the population is frequent enough to justify screening an entire population;
d) Whether appropriate and effective technology and trained personnel are available to perform the additional tests;
e) Whether resources for follow-up and counseling are available;

f) Whether resources and efficacious treatment are available; and
g) Whether the disorder is recommended for screening by any national professional organization such as, but not limited to the Secretary's Advisory Committee on Heritable Disorders of Newborns and Children, The American Academy of Pediatrics and the National March of Dimes.

Cite as Ga. Comp. R. & Regs. r. 511-5-5-.10
Authority: O.C.G.A. 31-2A-6, 31-12-5 through -7.
History. Original Rule entitled "Revisions to Newborn Screening Panel" adopted. F. May 13, 2014; eff. Jun 2, 2014.

Appendix B

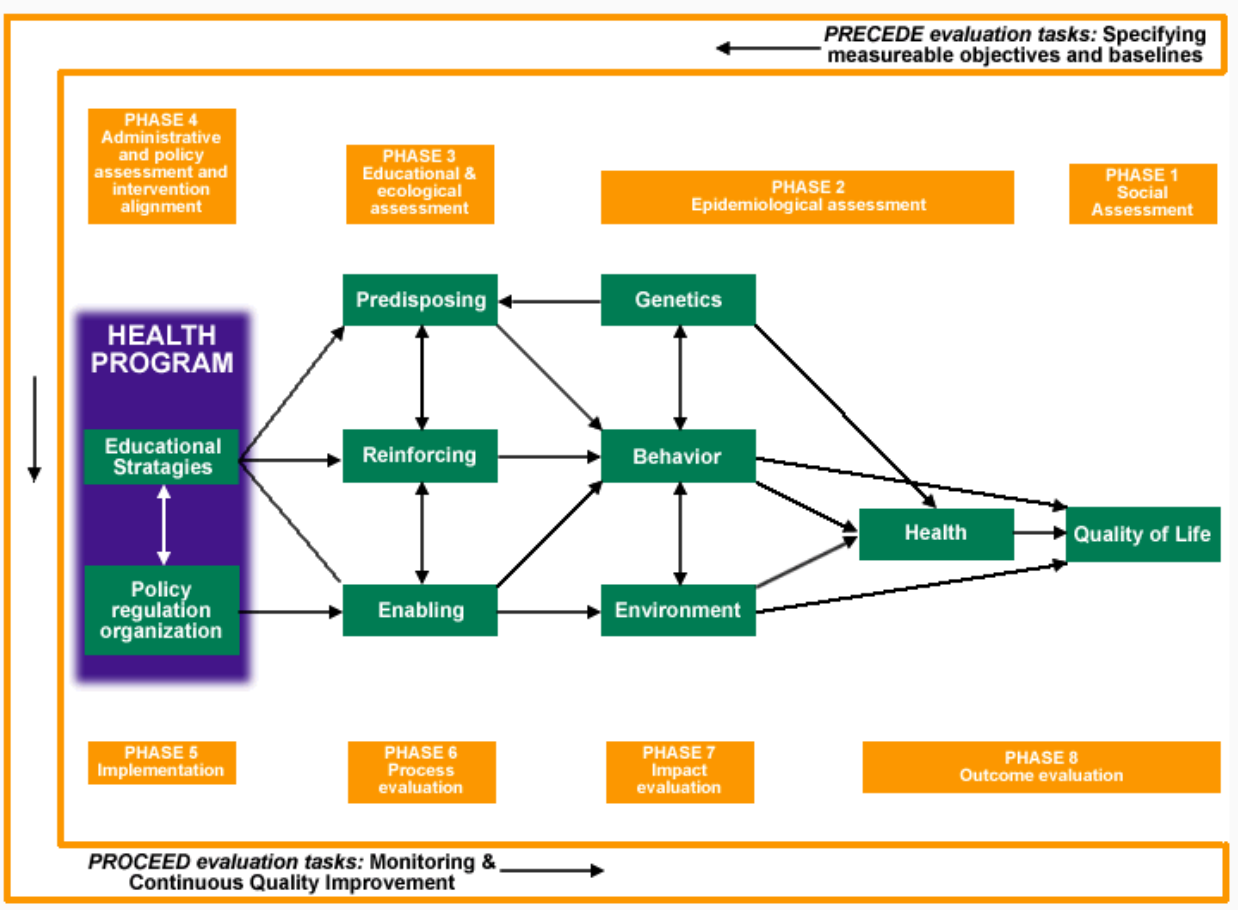

FIGURE 1. GENERIC REPRESENTATION OF THE PRECEDE-PROCEED MODEL. FROM L. GREEN AND M. KREUTER. (2005). HEALTH PROMOTION PLANNING: AN EDUCATIONAL AND ECOLOGICAL APPROACH (4 TH ED.). MOUNTAIN VIEW , CA : MAYFIELD PUBLISHERS.

Appendix C

EMORY UNIVERSITY | Institutional Review Board

October 6, 2015

Shelby Rentmeester, BA, MPHc
Department of Behavioral Science and Health Education
Rollins School of Public Health
Emory University
Atlanta, GA 30322

RE: Determination: No IRB Review Required
Title: *Impact of Change in Newborn Screening on Prevalence and Provider Perceptions in Georgia*
PI: Carol Hogue, Ph.D, MPH

Dear Ms. Rentmeester:

Thank you for requesting a determination from our office about the above-referenced project. Based on our review of the materials you provided, we have determined that it does not require IRB review because it does not meet the definition of "research" with human subjects or "clinical investigation" as set forth in Emory policies and procedures and federal rules, if applicable. Specifically, in this Public Health Practice project, you will conduct an email survey to those hospitals in Georgia that have identified as effectively or ineffectively making use of the Uniform Newborn Screening Specimen Card which was implemented in all Georgia hospitals by June, 2014. The Georgia Department of Public Health (DPH) is providing the necessary data (which contains identifiers), but will be sent to the study team as de-identified and the study team will only have access to related codes. The results will be used by DPH to formulate suggestions on how to improve the implementation of the new screening.

Please note that this determination does not mean that you cannot publish the results. This determination could be affected by substantive changes in the study design/aims. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Will Smith, MPH
Research Protocol Analyst

Appendix D

1. How many labor and delivery beds does this hospital have? _____
2. Please indicate what level nursery this hospital has:
    a. ____Well-baby/newborn (Level I) nursery
    b. ____ Special care (Level II) nursery
    c. ____ Neonatal intensive care unit (Level III) nursery
3. About how long ago did your hospital start conducting routine screening for CCHD using pulse oximetry for all babies in your well-baby/newborn (Level I) nursery?
    a. ____ More than 9 months ago
    b. ____ 6 to 9 months ago
    c. ____ 3 to 6 months ago
    d. ____ Within the last 3 months
        i. Skip pattern: only for those who indicated "Well-baby/newborn (Level I) nursery" for question 2
4. About how long did your hospital start conducting routine screening for CCHD using pulse oximetry for all babies in your special care (Level II) nursery?
    a. ____ More than 9 months ago
    b. ____ 6 to 9 months ago
    c. ____ 3 to 6 months ago
    d. ____ Within the last 3 months
        i. Skip pattern: only for those who indicated "Special care (Level II) nursery" for question 2
5. About how long ago did your hospital start conducting routine screening for CCHD using pulse oximetry for all babies in your neonatal intensive care unit (Level III) nursery?
    a. ____ More than 9 months ago
    b. ____6 to 9 months ago
    c. ____3 to 6 months ago
    d. ____Within the last 3 months
        i. Skip pattern: only for those who indicated "Neonatal intensive care unit (Level III) nursery" for question 2
6. If your hospital started screening longer than 9 months ago, what were some of the reasons why screening was initiated (*select all that apply*)?
    a. ____ Believe that it is cost-effective medicine
    b. ____ Concerned about missing an infant with CCHD
    c. ____ Required by our hospital's health system
    d. ____ Believe that CCHD screening is the new standard of care
    e. ____ Other (*please specify*)
    :_____
        i. Skip pattern: only for those who indicated "More than 9 months ago" for questions 3, 4, or 5
7. What were some of the barriers your hospital experienced in regards to implementing routine screening for CCHD (select all that apply)?
    a. ____ Need to purchase new equipment to carry out the screening
    b. ____ Need to hire new staff to carry out the screening

c. ____ No need for new staff or equipment, but concerned about reimbursement for cost of screening
d. ____ Unsure of how to report results
e. ____ No clear plan for follow-up of positive results
f. ____ Believe number of false positives will be too high
g. ____ Believe CCHD infants will be picked up through other mechanisms
h. ____ No barriers
i. ____ Other (*please specify*):_____

8. Do you feel the new screening forms take time away from providing the best care to the patient?
    a. ____ Yes
    b. ____ No
    c. If yes, please explain why:
9. On a scale of 1 to 4, how impactful does documenting results on the NBS Card have on best care (such as managing case load, and/or delivering timely care)?
    a. ____ Not impactful
    b. ____ Not really impactful
    c. ____ Somewhat impactful
    d. ____ Very impactful
10. On a scale of 1 to 4, how confusing is the NBS Card to use?
    a. ____ Not confusing
    b. ____ Not really confusing
    c. ____ Somewhat confusing
    d. ____ Very confusing
11. Do you feel the new screener improves the time to intervention for CCHD and hearing problems?
    a. ____ Yes
    b. ____ No
    c. If no, please explain why not:
12. Do you feel the newborns' parents perceive these screenings as beneficial to their child's health?
    a. ____ Yes
    b. ____ No
    c. If no, please explain why not:
13. How would you describe the process for screening patients in your hospital?
    a. ____ One person performs all screens
    b. ____ Different individuals are designated to perform each type of screen: CCHD, Hearing, or Bloodspot
    c. ____ Other (please specify)
14. What mechanism do you use to report the results of the screening tests?
    a. ____ NBS Card
    b. ____ Delayed Screening Report Form
    c. ____ Both NBS Card and Delayed Screening Report Form
    d. ____ Don't report
    e. ____ Other (please specify)

15. Please explain your reasoning for not reporting?
    a. Open Text
        i. Skip pattern: only for those who indicated “Don’t report” on question 14

Please provide your name and contact information and your institution’s name and location below. We will use this information for two reasons: 1) to follow-up on any questions we may have about your responses and 2) to ensure that we only received one response per facility. No hospital will be individually-identified with their responses. Data from this survey will only be presented in aggregate summary, with potential stratification by the number of live births (categorized), level of care provided, or current status of CCHD screening.

Name:_____

Phone:_____

Position:_____

Email:_____

Hospital name:_____

Hospital address:_____

Appendix E

Provider explanations for indicating "Other Method" of conducting newborn screening in the hospital

Hospital One (Level III): "The nurse caring for the baby at the time the screens are due is the one who completes the testing."
Hospital Two (Level III): "A few trained nurses perform the hearing screens, every nurse in the unit does their own CCHD and newborn screening themselves."
Hospital Three (Level I): "Neonatal staff completes initial screenings. Any recollected Bloodspot are obtained by lab."
Hospital Four (Level I): "All of the staff is trained to do all of them and whoever is caring for the patient does it."
Hospital Five (Level I): "Who ever does the discharge."
Hospital Six (Level I): "Three staff nurses perform all three of the screenings."
Hospital Seven (Level I): "Discharge nurse does the screening."
Hospital Eight (Level I): "The nurse caring for the infant does all of the screening at the appropriate time."
Hospital Nine (Level II): "Done at 24 hours of age by whichever nurse has that [patient] at that time."
Hospital 10 (Level II): "Hearing is done after delivery and bath is done by the nurse on duty, CCHD and bloodspot are done by which particular nurse is on duty at the time, depending on rotation schedule."
Hospital 11 (Level I): "The nurse assigned to do newborn care does the screenings-All nurses trained to do screenings."
Hospital 12 (Level III): "Different individuals perform screenings depending on when they are completed. Audiologist does hearing screening, and nurse does bloodspot and cchd (but no designated individual). These may be completed on different days."
Hospital 13 (Level III): "PCTs do them mostly but nurses are checked off to do this also."
Hospital 14 (Level I): "Primary nurse for that shift may perform all screens or just 1 or 2 of screens. All screens will be done and documented before discharge."
Hospital 15 (Level III): "Our hospital sub contracts hearing screens thru Pediatrix. The nurse caring for the infant is responsible to obtain CCHD as well as the blood spots."
Hospital 16 (Level II): "All nurses and nurse techs are trained/certified to do all 3 screenings."