Policy Analysis Paper: Proposed Change to Texas House Bill 740

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Introduction

Research conducted by the March of Dimes indicates that an estimated 35,000 infants are born each year with a congenital heart defect (Birth Defects, 2013). The American Academy of Pediatrics (AAP), states that one quarter of these children will have Critical Congenital Heart Disease (CCHD), which by definition requires surgery or catheter intervention within the first year of life (CDC, 2012). Early diagnosis and intervention is required in order to minimize and/or prevent the associated hypoxemia, shock, and acidosis, which may result in organ damage and possibly death.

Some families are fortunate enough to have the defect diagnosed prenatally; others however, find themselves in an emergency room with their newborn days after delivery. The State of Texas recently enacted legislation to preform congenital heart defect screening on newborns born in a birthing facility prior to discharge home.

Specific health policy to change

Texas House Bill 740, introduced by Representative Myra Crownover, requires that all newborns born within a birthing facility in the state of Texas receive basic screening for CCHD prior to their discharge. This bill was approved by both the House and Senate of the State of Texas, and on June 14, 2013 was signed into law by Governor Rick Perry. Although this bill was recently signed by the Governor, it will quickly be enacted into law on September 1, 2013 (History (n.d.) In Texas Legislature Online, 2013)

CCHD screenings can be non-invasively conducted by using pulse oximeter monitors. Pulse oximetry sensors are attached to an infant’s right hand and either foot in order
to monitor hemoglobin oxygenation. An abnormal screen (low pulse oximetry reading) may alert providers to conduct more specialized testing (CDC, 2013). This test can be completed within 5-10 minutes and may help target the following congenital heart defects: hypoplastic left heart syndrome, pulmonary atresia, tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus. Other cardiac defects found through the use of this screening may include coarctation of the aorta, double outlet right ventricle, Ebstein anomaly, interrupted aortic arch, or single ventricle lesions (Screening, 2013).

Proposed change

Our group proposes an amendment to House Bill 740. Currently the new bill mandates congenital heart screening on all infants born within a hospital or licensed birthing center. We propose extending CCHD screening to infants born at home. In 2009, the National Center for Health Statistics estimated that there were over 29,650 home births within the United States (0.725%). This 29% increase from 2004 shows the rise in popularity of home births (MacDorman, Mathews & Declercq, 2012). Our proposed amendment would require all infants born at home to be seen by a medical provider trained to conduct CCHD screening within the first 24-48 hours of life. Parents would have two options; first they may take their infant to a trained medical provider, such as a pediatrician, in order to be screened. Another option would be for medical personnel assisting with the home delivery, such as a midwife, to return to the home in 24-48 hours to conduct the screening.

Historical development of the policy and related health issue
Evidenced based research conducted from 1966 to 2008, acknowledges the importance of routine screening for the identification of congenital heart defects in neonates (Mahle, Newburger, Matherne, Smith, Hoke, Koppel, . . ., Grosse, 2009). Recent evidence shows that screening for CCHD early in life significantly decreases rates of infant morbidity and mortality (The Patient Safety Movement, 2013). The most cost effective, timely, and accurate screening measure identified is the use of the pulse oximeter. Guidelines have been created to use the pulse oximeter within 24-48 hours based on the CDC algorithm, which uses pre and post ductal oxygen saturation measurements for identification of CCHD in newborn infants.

In 2011 members of the AAP, the American College of Cardiology Foundation, and the American Heart Association recommended a standard screening process to the United States Health and Human Services (HHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) (The Patient Safety Movement, 2013). This recommendation endorses routinely screening each newborn, delivered in a birthing facility, for CCHD with the use of pulse oximetry. In September of 2011, the US HHS approved the endorsement of the screening as proposed by the SCCHDNC.

**Socio-economic factors related to development of the policy**

Several socio-economic factors have contributed to the mis-diagnosis of CCHD in neonates. The use of prenatal ultrasound can detect CCHD, but the availability of ultrasound may be limited in women of certain racial, ethnic, and low socio-economic groups (Mahle, et al., 2009). Another method for identifying structural abnormalities is through neonatal echocardiogram. While this procedure is often considered a definitive diagnostic modality, it is often costly and requires highly specialized personnel for interpretation.
Although extensive research has identified pulse oximetry as one of the most effective and reliable methods of screening for cardiac abnormalities, its increased use has raised concerns regarding inaccurate monitoring among different racial groups or ethnicities. “At low SpO\textsubscript{2} levels (<70%), commercially available oximeters appear to overestimate arterial saturation by 3% in darkly pigmented subjects.” (Mahle, et al., 2009) This may result in mis-diagnosis in darkly pigmented infants. Additionally, in these populations, cyanosis maybe more difficult to identify and therefore delay the need for pulse oximetry monitoring.

Families living in rural areas may be less likely to have access to specialized diagnostic methods. The availability of high-risk specialist or pediatric cardiologist in rural areas may be limited (Mahle et al, 2009). This may leave infants to have echocardiograms performed by sonographers and cardiologists with no pediatric training. “Several investigators have found that the accuracy of pediatric echocardiograms interpreted by adult cardiologists is low.” (Mahle et al, 2009). Without pediatric trained specialist, incorrect interpretations of these tests are possible, leading to unnecessary procedures, time and stress.

In implementing this policy, we must highlight the advantages of using the pulse oximeter: minimal equipment, training, and time. The tools and personnel are readily available in hospitals and birthing centers in both rural and urban areas. Conducting a screen before the discharge of an infant can uncover an unknown defect, and therefore prevent unnecessary future costs and procedures. When extended to home births, the use of pulse oximetry will provide monitoring to those populations who choose to forego traditional hospital births.

**Legal factors that contributed to development of the policy**

In its policy statement endorsing universal CCHD screening, the American Academy of Pediatrics (2011) acknowledges that although the Secretary of the Department of Health and
Human Services has recommended CCHD screening be added to the Recommended Uniform Screening Panel (RUSP), each state must individually decide how to integrate CCHD screening into their newborn screening programs. The AAP further states that this may be accomplished through legislation, regulation, or adoption of CCHD screening as a standard of practice (Mahle, Martin, Beekman III, Morrow, Rosenthal, Snyder,... & Tweddell, 2012). On August 31, 2011 New Jersey became the first state to pass legislation mandating the universal screening of CCHD among all newborns. As a result of this new legislation, New Jersey hospitals reported 12 newborns with initial positive screens, and 2 confirmed cases of CCHD during the first 3 months of the program’s implementation (CDC, 2013). Since then, 18 states, including Texas, have introduced or instituted legislation mandating universal newborn screening of CCHD (CDC, 2013).

**Ethical issues related to development of the policy**

New technologies, legal, and social factors raise ethical concerns regarding newborn screening programs. Technological advances have allowed for a rapid increase in the number of screenable disorders, including CCHD. This pressures state health departments to expand their newborn screening list. Additionally, it raises questions regarding how policy is developed to address screening; the limits of public health responsibility; and the demands on healthcare systems in providing treatment when screening results are positive (Kenner, Lewis, Pressler, & Little, 2008).

The state-to-state variability that exists among newborn CCHD screening programs raises concerns regarding the equality of screening among populations. Due to a lack of mandated national standards for testing, states must individually decide what conditions to screen their citizens for (Kenner et al., 2008). This leaves states to ponder and weigh the morbidity and
mortality associated with congenital heart disorders. Ultimately, each state must independently decide on whether or not to conduct screenings on its population.

Inclusion of a disorder, such as CCHD, onto a state’s screening list is often influenced by factors such as local advocacy, pressure from parental groups, and economic interests. This creates a problem because parental advocacy groups often present arguments for expanded testing that are based on personal and anecdotal experiences instead of scientific evidence. Furthermore, these advocacy groups are often times funded by pharmaceutical or medical technology companies with a vested interest in promoting the treatments they are developing (Ross & Waggoner, 2012). Another ethical concern with parental advocacy groups is that they do not represent the views of all parents. In allocating resources for these screening programs, states must consider the risks and benefits to all newborns being tested; even those whose parents may be less likely to engage in legislative and advocacy efforts (Ross & Waggoner, 2012).

**Affect on nursing practice**

The mandatory implementation of CCHD screening will have a direct affect on nurses in hospitals and birthing centers, Neonatal Nurse Practitioners who treat newborns, and nurse midwives who attend home deliveries. Nurses performing the screening will be required to attend an educational training program prior to the implementation of CCHD screening in their practice. Education should include, importance of the screen, educating families, operation of necessary equipment, steps to perform the screen, and correct interpretation of results.

Nurses must also be able to adequately assess screening results. There are many factors that may influence the screen, and the administrator must able to identify when a screen should be repeated and when the results are accurate. For example, was the infant crying and vigorously
moving, thus affecting the pulse oximetry reading? Was there an adequate waveform for the duration of the exam? A research study by the American Heart Association and the AAP recognized some screens show a falsely low oxygen saturation with feeding, crying, sleep, movement, poor perfusion, hyperbilirubinemia, and improper probe attachment (Mahle et al, 2009). The nurse must recognize when to repeat the test, in order to verify questionable results, and when he/she must contact a physician immediately.

With the implementation of House Bill 740, additional time will be required by nurses to perform the screen, properly educate family member, and follow up if necessary. The CDC estimates that barring any additional tests being required, it takes less than ten minutes to screen each infant (Screening, 2013). Midwives and other personnel who attend home deliveries may be more affected if the parents insist that the screening is performed at home. This would require the midwife to return to the home after 24-48 hours of the infant’s birth in order to accurately assess the infant’s oxygen saturations. If further follow up tests are indicated, the midwife could assist the families in arranging follow up tests and procedures. Considering that over 35,000 infants are born each year with a CCHD (March of Dimes, 2013), the additional education, time, and resources required to perform this life saving screening are justifiable.

**Affect on health care delivery**

The use of universal newborn CCHD screening will not only serve to identify critical heart defects, but will also allow for the cumulative collection of data, tracking, and analysis for research purposes (March of Dimes, 2013). The data obtained can identify prevalence trends, and recognize the different distributions of CCHD between states (March of Dimes, 2013). The information collected will demonstrate which locations have a higher incidence of CCHD, and
serve to increase awareness, education, funding, and legislation in those regions. This will allow healthcare providers to be adequately equipped and prepared to initiate screening programs. By identifying CCHD early, patient outcomes can be improved; morbidity and mortality among the neonatal population can be reduced; and unnecessary costs associated with emergent re-admissions and undiagnosed defects eliminated. This will result in an overall improvement to the healthcare delivery system.

Affect on health care consumers

Undetected CCHDs can increase the risk for serious complications such as end-organ damage, motor function impairments, and cognitive impairments (CDC, 2012). Emergent medical care with multiple procedures, labs and consults is required to diagnose and treat undetected heart defects. Implementing universal screening of CCHD among newborns would help to identify defects early and reduce the risk of complications. This is of great benefit to health care consumers.

In addition to serious health complications, the financial burden on families of CCHD infants is enormous. In 2005 the medical care costs of a single infant with CCHD were $100,000 (CDC, 2011). The CDC (2011) estimated that in 2004 the overall cost associated with CCHD in the United States was $511 million. Furthermore, it is estimated that 300 infants are discharged from the hospital yearly with an undiagnosed CCHD. This statistic does not account for infants delivered at home (Screening, 2013). Implementing screening programs will help to reduce the number of infants who go undiagnosed, and eliminate some of the associated costs.

With the implementation of this new policy and practice change, the potential for some increases in healthcare also costs exists. CCHD screening is estimated to cost approximately $15
per infant (Screening, 2013). This cost includes the pulse oximeter probe, adhesive tape, equipment, and staff time spent conducting the screening. In addition to the $15, if an infant is suspected of having a CCHD then healthcare cost associated with a pediatric cardiology consult, and an echocardiogram will be incurred. If a confirmed diagnosis results, then the costs of surgical correction and long term medical care will have to be factored in.

**Summary**

With this policy change and implementation, ethical, legal, and socioeconomic factors were considered, as well as their impact on health care delivery, consumers, and nursing practice. Through evidenced based research and legislative changes initially seen in New Jersey in 2011, screening for CCHD has been found to aid in the early recognition of defects, and ultimately has directly reduced infant morbidity and mortality. The 29% rise in home births, will result in an increased number of infants who will not be screened for CCHD (MacDorman et.al, 2012). The proposed amendment to HB 740 would include screening of those infants born at home, and provide equal, high quality care to all infants born within the state of Texas.
References


