Pulse Oximetry Screening for Critical Congenital Heart Disease in Planned Out-of-Hospital Births

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Objectives To describe the use of pulse oximetry screening (POS) for critical congenital heart disease (CCHD).

Study design This observational study of Wisconsin out-of-hospital births was performed from January to November, 2013. Licensed midwives, Amish birth attendants, and public health nurses were trained in the use of pulse oximetry to detect CCHD, supplied with pulse oximeters, and reported screening results and clinical outcomes.

Results Results of POS in 440 newborns were reviewed; 173/440 births were from Amish or Mennonite communities. Prenatal ultrasonography was performed in less than one-half of the pregnancies and in only 13% of Amish and Mennonite women. A total of 432 babies passed the screening, 5 babies were incorrectly assigned to have passed or failed, and 3 babies failed the screening. Two of the babies who failed the screening were treated for sepsis and the third had congenital heart disease. There was 1 false negative result (coarctation of the aorta and ventricular septal defect).

Conclusions This study provides information on the use of POS for CCHD in out-of-hospital births and shows that POS can be successfully implemented outside the hospital setting. Although the failure rate in this small sample was higher than reported in studies of hospital births, those babies failing the screening had significant disease processes that were identified more rapidly because of the screening. *(J Pediatr 2014;165:485-9)*.

Critical congenital heart disease (CCHD) affects 1-3/1000 babies born in the US every year.[1-4] The majority of these infants are diagnosed by prenatal ultrasound or by clinical examination shortly after birth. However, a subset of infants with CCHD will be missed by both prenatal ultrasound and clinical examination and may present with significant cardiac morbidity or mortality in the neonatal period.[5,6] Recent efforts to screen infants for CCHD with pulse oximetry screening (POS) have focused on identifying infants with clinically undetectable CCHD prior to discharge from the birth hospitalization.[7-10]

The US Secretary of Health and Human Services recommended universal newborn POS for CCHD in September 2011. The American Academy of Pediatrics endorsed these recommendations in December 2011[11] and in 2013 included a recommendation for POS for planned home births.[12] All screening recommendations are based on evidence derived from babies born in the hospital setting, and little is currently known about POS in the out-of-hospital (OOH) birth population. According to the Centers for Disease Control and Prevention, the number of OOH births increased from 0.56%-0.72% of US deliveries between 2004 and 2009.[13] Wisconsin had the fifth highest rate of OOH delivery in the nation with 1.66% of births occurring at home or in a birthing center.[13]

Midwifery standards of practice for OOH birth in Wisconsin are defined by the State Department of Safety and Professional Services. Licensed midwives are required by the rules and regulations guiding their practice to remain with the mother and baby after birth until the both mother and baby are stable and for no less than 2 hours. On average, midwives report staying 3-4 hours after birth. They are also required to reevaluate maternal and infant well-being within 36 hours of birth. The timing of this reevaluation is subject to medical indication, clinic schedules, weather, distance to the home, and the preferences of the family. Newborn blood screening is typically performed at this visit. Hearing screening may also be performed at the same visit, or deferred to a subsequent appointment.

Some families, particularly members of plain clothes communities, have unattended deliveries or use a birth attendant who is a member of their community. The training, experience, and newborn care practices of these nonlicensed birth

CCHD	Critical congenital heart disease
OOH	Out-of-hospital
POS	Pulse oximetry screening
SHINE	Screening Hearts in Newborns

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attendants are highly variable. Previous data collected in Wisconsin suggest that the incidence of missed or delayed diagnosis of CCHD is significantly higher in the OOH birth population (1/2684) than among hospital born babies (1/28 350).[6]

Methods

To further understand the role of POS for CCHD in the OOH population, the Wisconsin Screening Hearts in Newborns (SHINE) Project has included the OOH birth population in a 3-year statewide project designed to provide information on POS, assist in the implementation of POS, and evaluate the performance of POS in hospital and OOH settings. All hospitals and licensed midwives in the state of Wisconsin were invited to participate with ongoing enrollment beginning January 1, 2013. The SHINE Project is a collaborative effort between the University of Wisconsin, the Medical College of Wisconsin, the Wisconsin Guild of Midwives, the Wisconsin Department of Health Services, and the Wisconsin State Laboratory of Hygiene and is funded by a demonstration grant from the Health Resources and Services Administration (a branch of the US Department of Health Services). The functions of the Wisconsin SHINE project were reviewed by the University of Wisconsin Health Sciences Institutional Review Board and determined to be quality assurance measures and not human subject research. The assessment of POS in the OOH population presented in this article was also evaluated using the "Not Research Determination Decision Tool" prepared by the University of Wisconsin Health Sciences Institutional Review Board and was again determined to not to be human subjects research. A discussion of the advantages and disadvantages of prenatal and postnatal screening is a routine part of the midwives' practice and patient level discussion of the SHINE project, and its data collection with each mother was the responsibility of each participating midwife.

Licensed midwives belonging to the Wisconsin Guild of Midwives were trained in the use of POS to detect CCHD and the use of a handheld pulse oximeter approved for use in infants by the Food and Drug Administration[14] (Masimo Rad5v; Masimo Corporation, Irvine, California). Participating midwives offered POS to their clients with screening and reporting performed on a voluntary basis. POS was done according to the protocol recommended by the US Secretary of Health and Human Services.[15] The recommended time for screening was between 24 and 48 hours after birth, and oxygen saturation was measured in the right hand and either foot using a Masimo Rad5v (Masimo Corporation) handheld pulse oximeter and a reusable probe designed for use with the Masimo oximeter (Masimo Corporation). All midwives used a reusable probe but carried a disposable probe in case of failure of the reusable probe. Midwives continued to enroll throughout study period. Late in the course of the project, 2 Amish birth attendants and 2 public health nurses working with the plain clothes community were also enrolled in the Wisconsin SHINE project and received the same training as the licensed midwives.

Infants were considered to pass the screen if oxygen saturation was ≥95% in the hand or foot and there was ≤3% difference in saturation between the hand and the foot. Infants were considered to fail the screen of oxygen saturation was <90% in the hand or foot. An equivocal reading was ≥90% and <95% in hand and foot or ≥3% difference between hand and foot. In the case of an equivocal reading the screen was repeated in 1 hour. The screen could be repeated twice with the same criteria for pass, fail, or equivocal. An infant with 3 equivocal results was considered to have failed.[15] The phrase "two sites/three strikes" was used to remind providers of the algorithm. Each midwife was given laminated copies of the screening protocol. The protocol was also available online on the SHINE project website (www.wisconsinshine.org). The presence of 1 of the 7 primary or 5 secondary target CCHD lesions was the endpoint of the POS algorithm.

Infants who passed the POS required no further evaluation. A protocol was established for failed screening that included contacting a "hotline" that would respond to questions regarding the algorithm or data collection methods and would provide consultation and clinical support for any infant failing the screening. Access to an on-call pediatric cardiologist was available to the participating midwives at all times. The role of the on-call pediatric cardiologist was to provide clinical guidance and to facilitate the medical evaluation of babies when appropriate. This remote assistance also included contact with the medical facility receiving the baby to review the implications of a failed POS. Midwives were encouraged, although not required to investigate the resources available locally to assess those infants who failed their POS before incorporating it into their practices.

The American Academy of Pediatrics guidelines recommend a "comprehensive evaluation for causes of hypoxemia" prior to performance of echocardiography to exclude CCHD.[15] Options for referral of babies failing their POS depended on the location and clinical status of the infant and the resources available at the nearest medical facility. Neonatal echocardiography was available in only 37.5% of the Wisconsin hospitals responding to a 2011 survey on POS.[16] Options for evaluation included referral to the nearest hospital that could evaluate for causes of hypoxia but could not perform echocardiography, referral to the nearest hospital that had neonatal echocardiography available, or partnering with a local physician to evaluate hypoxia in a clinic or urgent care facility. For infants referred for evaluation where no echocardiogram was available, infants could be transferred to higher level of care for echocardiogram based on the assessment of local providers with echocardiography recommended for those babies without an explanation for their hypoxia.

Results of the POS (pass/fail/not screened) were recorded on the state newborn screening blood card and submitted to the Wisconsin State Lab of Hygiene. Midwives also completed a more detailed data set that included basic