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Home is Where the Heart is: Critical Congenital Heart Disease Screening in Homebirths

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Critical Congenital Heart Disease Screening in Homebirths

Congenital heart defects (CHD) are the most common group of congenital malformations with an incidence ranging from 4-10 cases out of 1,000 live births (Amsbaugh et al., 2015; Bradshaw & Martin, 2012; Ewer et al., 2012; Plana et al., 2015). Further, CHDs are the leading cause of infant death in the developed world, accounting for 6% to 10% of fatalities (Harold, 2014). The incidence of *critical* congenital heart defects (CCHD) account for 15%-25% of all CHDs respectively occurring in 3/1,000 live births in the United States annually, and account for 30% of infant fatalities annually (Amsbaugh et al., 2015; Bradshaw & Martin, 2012; Harold, 2014; Plana et al., 2015).

CCHD refers to any congenital, ductal-dependent defect. The critical nature of these defects is that adequate circulation is reliant upon a patent ductus arteriosus (PDA), which is potentially life threatening if surgical repair and intervention are not received within the first 28 days of life (Amsbaugh et al., 2015; Ewer et al., 2011; Oakley, Soni, Wilson, & Sen, 2014). Due to the newborn's dependence on a PDA for hemodynamic stability it is imperative to detect a CCHD before the natural closure of the ductus arteriosus within the first hours of life (Crouch, Speroni, Jones, MacDougall, & Daniel, 2016; Ewer, 2014; Mellander, 2013). Without early detection, severe hypoxemia and circulatory collapse develop, which in turn leads to shock and acidosis, organ damage, and ultimately death (Amsbaugh et al., 2015; Crouch et al., 2016, Ewer, 2014; Mellander, 2013; Oakley et al., 2014).

In 2011, the Secretary of Health and Human Services (HHS), with strong backing from the American Heart Association (AHA), American Association of Pediatrics (AAP), American College of Cardiology Foundation, and March of Dimes, endorsed the screening for CCHD in all newborns through the use of pulse oximetry, recommending that it be added to the current

Recommended Uniform Screening Panel (RUSP) (Ailes, Gilboa, Honein, & Oster 2015; Amsbaugh et al., 2015; Bradshaw & Martin, 2012; Ewer, 2014; Harold, 2014). The AAP (2016b) recommends that all newborns, who have not already been diagnosed with a CCHD in utero, receive the CCHD screen at 24 hours of life. This recommendation was for all births, whether they occur in hospital or in planned homebirths.

As of May 2nd, 2016, 36 states, including the District of Columbia, have passed laws that require the CCHD screen in hospitals, and 11 states have regulations or guidance in place for the screen (AAP, 2016a). In Oregon, Senate Bill 172 (2013) requires all hospitals and birthing centers to perform the screen. However, there is a practice gap as newborns who are delivered in planned homebirths are not required to be screened. With the increased numbers of planned deliveries outside of hospital setting, newborns with CCHD are at an increased risk of being missed during the early critical period. Instead, they will not be diagnosed until later, when signs and symptoms become evident as the ductus begins to close (Amsbaugh et al., 2015; Hoffman, 2011).

According to the Oregon Health Authority's (OHA), the number of planned homebirth deliveries remains consistently near 1,000 live births a year (see Appendix A, Table A1). Taking into account that the estimate of CCHD occurrence is 3/1,000 live births it is reasonable to assume that at least three newborns born at home will potentially have a CCHD.

The purpose of the project was to partner with Midwifery Care© to implement a process for the CCHD screen in the homebirth setting. The goal was to develop a hybrid training module, provide supervised training, , and then proceed to measure the percent of newborns who are screened, as well as analyze the results of the screen over a six month period. The data

provided would then be used to examine the effectiveness of a hybrid training module and the feasibility in implementing the CCHD screen in the homebirth setting in Oregon.

Literature Review

Search Methodology

A review of literature was performed to explore the efficacy of pulse oximetry as part of the newborn screen in detecting CCHDs. Three electronic literature searches were performed (for complete search details see Appendix B, Figure A1). The initial search (February, 2016) was the most extensive using the Ovid MEDLINE search engine. The final number of articles from the initial search was 37 articles. A second search (February, 2016) was performed using PubMed (MEDLINE) alone resulting in 13 articles to review. The third search (May 2016) was performed using CINHALL, and this final search resulted in 1 article.

The full articles of all three searches, 51 total articles, were selected to be reviewed. Of note, one of these articles was unable to be obtained resulting in 50 articles printed and manually reviewed. The exclusion criteria applied during the manual review was determined based on the efficacy of pulse oximetry screening in asymptomatic term newborns, and reviews of state studies that had a low number of newborns screened did not provide a broad enough picture due to the ratio of CCHD in live births.

The final number of articles reviewed for this project totaled 18 articles (see Appendix C, Table A2). During the literature review process the predominant focus was the sensitivity and specificity of pulse oximetry in detection of CCHD, and review of studies performed in the homebirth setting.

Synthesis of Literature

Throughout the literature there are findings of variations of the methods to obtain pulse oximetry readings, especially in terms of limb placement, obtaining post-ductal versus pre-/post-ductal saturations, optimal timing of screening, and the threshold for abnormal results (Amsbaugh et al., 2015; Ewer, 2013a; Thangaratinam et al., 2012). A systematic review and meta-analysis described in two of the articles looked at 13 different studies, totaling 230,000 newborns who were screened for CCHD using pulse oximetry. The results reflected a moderate sensitivity (76.5%; 95% CI 67.7-83.5) and a high specificity (99.9%; 95% CI 99.7-99.9) (Ewer, 2013b; Fillips & Bucciarelli, 2015). Four of the most recent large population-based studies showed similar results (see Appendix D, Table A3) The findings of the systematic review and meta-analysis shows the CCHD screening, using pre-/post-ductal oximetry, meets the criteria for implementation as a universal screen (Ewer, 2013b). Pulse oximetry is not a perfect test on its own with a sensitivity 75% for CCHD meaning $\frac{1}{4}$ of cases are undetected when not performed with physical exam (Ewer, 2013a; Ewer, 2013b).

The CCHD screen relies upon the use of pulse oximetry, which is a common method for monitoring and has been in use for over 30 years (Ewer et al., 2012; Plana et al., 2015). Pulse oximetry is a quick, painless, non-invasive, and reliable indirect method for determining arterial oxygen saturation that can be used to identify clinically undetectable hypoxemia that is present in some degree in CCHDs (Ewer, 2013b; Ewer et al., 2012; Ewer et al., 2011; Pflugeisen et al., 2015). Studies have shown that pulse oximetry screening can detect seven major CCHDs including hypoplastic left heart syndrome (HLHS), pulmonary atresia, tetralogy of Fallot (TOF), total anomalous peripheral venous return (TAPVR), transposition of the great arteries (TGA), tricuspid atresia, and truncus arteriosus. Although less common, coarctation of the aorta and

interrupted aortic arch may also be picked up with the CCHD screen (Plana et al., 2015). Of note, although the primary purpose of the screen is to detect potential CCHDs, there is evidence that the screen detects other major medical conditions that cause hypoxia such as sepsis, group B *streptococcus*, congenital pneumonia, and pulmonary hypertension (Ewer, 2014; Ewer et al., 2012; Ewer et al., 2011).

Although the AAP (2016b) recommends screening newborns delivered in the homebirth setting, the literature search produced only one study (conducted in the United States) on implementation of the CCHD screen in birth settings outside of the hospital. The 2013 Wisconsin *Screening Hearts in Newborns* (SHINE) Project trained 29 licensed midwives, two Amish birth attendants, and two public health nurse on how to perform the CCHD screen (Lhost, Goetz, Belling, Van Roojen, Spicer, & Hokanson, 2014). The study was conducted over eleven months and produced promising results (see Appendix E, Table A4). The literature supports the efficacy of the screen. Together with the SHINE project, there is sufficient evidence to support the implementation of the screen in the homebirth setting.

Approach to the Conduct of the Project

Setting

The project was designed for the homebirth setting. A web-based search for midwives with a practice focus in homebirths located in Eugene, Oregon was conducted. These midwives were contacted through email to recruit providers who may be interested in taking part of the project. One practice, Midwifery Care©, was the only practice that responded. The lead licensed midwife is the sole proprietor of the practice and employs one other midwife.

Function and purpose. Midwifery Care© serves clients who are planning to have a homebirth. The function of the midwives in this setting is to inform, provide guidance and care

prenatally, attend the labor and birth keeping both the mother and neonate safe, and to provide postpartum care for the newborn and mother.

Anticipated barriers and/or challenges. The anticipated barriers and challenges included: 1) acceptance of the screen by midwives and parents, 2) lack of training and knowledge of CCHD protocols and use of a pulse oximeter for the screen, 3) concerns for cost effectiveness of both the screen and the pulse oximeter, 4) concern about the effectiveness of the pulse oximeter, and 5) the lack of an existing partnership between the midwifery practice and the local pediatric cardiologist at the nearby hospital. The main concern the midwives conveyed was the fear of developing a dependence on the pulse oximeter reading. Accordingly, the training module for CCHD screening was specifically designed to address barriers and the midwives concern about technology dependency.

Population

The project was designed so that the midwives would perform the CCHD screen at each homebirth they attended over a six-month period. Inclusion criteria of newborns included final method of delivery in the client's home, healthy, and at least 24-72 hours old. Newborns who had been identified prenatally with a CHD or CCHD, transported to the hospital for final method of delivery, or requiring resuscitation efforts immediately after birth would be excluded. The parents would receive information about the CCHD screen before the estimated date of delivery, and may either sign a consent form or a refusal form. The screen would not take priority in the care of the newborn in the event of evident distress.

Proposed Implementation and Outcome Evaluation

Implementation Procedures

After a partnership with a local midwifery homebirth practice had been established, the pediatric cardiologist at the nearby hospital was to be contacted for recruitment to participate in this project. To implement this project a hybrid training module, based on the AAP CCHD screening guidelines, and specific for homebirths was developed. The training module was designed so that the midwives would participate in the training and pass both a skills evaluation as well as a written exam. The midwives would have also been supplied with a pocket-sized laminated card of the screening algorithm for quick reference during screens. The midwifery practice had already purchased a FDA-approved, reusable pulse oximeter for the purpose of using it for the CCHD screen.

An educational pamphlet about the CCHD screen, tailored to parents who are planning a homebirth, was developed. The goal of developing the pamphlet was that midwives would present it to the parent(s) during a predetermined prenatal office visit. During that visit the midwives would answer any questions the parents have concerning the screen, and obtain consent or document refusal.

Proposed Measures

To evaluate assess the training module, a pre- and post-training questionnaire was developed. This part of the evaluation looked at knowledge acquisition. To evaluate uptake of knowledge gained from the training module the midwives were to record their screening activities and data over a six-month period, as outlined on the developed data collection form for implementation analysis. The proposed data for collection was based on the suggestions found in the 2016 AAP Guidelines (Appendix F, Table A5). Weekly check in meetings/calls were to be

conducted with the midwives to provide support for tracking data, and to address any questions or barriers that emerged. At the end of the six-month study, the midwives would also then be asked to evaluate their overall experience, as well as provide feedback for suggested changes to the module, training, or tracking.

Proposed Contribution to Practicum Site

The goals of this project were to improve patient care through training and tools for the midwives; assist and promote implementation of screening in homebirths; and develop a partnership with the local pediatric cardiologist. The midwives also expressed a desire to share their experience with other local midwives and recruit them to implement the screen in their own practice.

Implementation of the Proposed Project

The proposed project was not fully implemented due to several factors that arose. The primary challenge was communication. It was difficult to obtain timely replies for setting up face-to-face meetings, as well as scheduling a time for training. Despite their interest and agreement to participate in the project the practicum site voiced several concerns. The concerns that were expressed by the practicum site included: 1) the amount of time required to participate in a student led project, and 2) the refusal to allow the student to observe the role of the midwife in a homebirth. This stemmed from the practicum site's philosophy that strangers, even students, should not be present in an environment where a trusting relationship has been established between the midwife and the family. The most significant factor that prevented full implementation of the project was the midwife eventually opted to pull out of the project, due to other extenuating circumstances. This meant that the project could not be completed as conceived.

Although the implementation was unsuccessful, there was a lot of learning and the framework and process for future attempts was accomplished. First and foremost, an interactive, voice-over, online training module was developed and recorded. Second, an educational pamphlet was created about CCHD screening for the midwives to share with expecting parents. Third, the AAP screening algorithm was made readily accessible and portable, by being transferred to laminated cards which the midwives could reference when performing the screen. Fourth, a Survey Monkey website was developed to include the three newly created questionnaires that were to be used for evaluation of the hybrid training module and implementing the screen in practice. Finally, the training materials for skills assessment, as well as the written exam and skills checkoff sheet, were developed. In summary, while not implemented and evaluated, the module, training, and evaluation materials were created and ready for implementation.

Practice-related Recommendations

The SHINE Project discussed earlier showed that the CCHD screen can be successfully implemented in the homebirth setting. The design of Wisconsin's project used an in-person method to train those who would be performing the screen in planned out-of-hospital births. The time constraints of a practicing midwife, as well as the spontaneity of when clients go into labor, was the key consideration when developing the hybrid training module for the current project. The intent was for the midwife to be able to complete the online portion on her/his own time. The online module not only had the voiceover presentation, but the added benefits of allowing the midwife to pause the module if needed and to take the written portion of the exam with real-time feedback. After completing the online module, the midwives would then attend a one-hour skills training and competency assessment in person.

With the growth of technology many schools and training programs have adapted hybrid learning modules to accommodate distance learners and busy lifestyles. A two-year pilot study was conducted to evaluate the effectiveness of a hybrid learning system compared to traditional classroom learning for paramedic students (Newberry, 2015). The study evaluated both groups using Health Education Systems Inc. (HESI) test scores, psychomotor exams based on the National Registry of Emergency Medical Technicians guidelines, and the students' competency in managing case-based simulations in-person. Over the two-year study, 27 traditional students and 77 hybrid students participated in the pilot program. The mean HESI score ($M=626$) was lower for traditional students when compared to the hybrid students ($M=690$) (Newberry, 2015). The study was conducted for another two years, from 2012 to 2014, to assess if the results from the first study could be repeated. This evaluation consisted of 68 traditional students and 222 hybrid students. This study confirmed the results of the first study showing that hybrid training ($M=679$) has equal, if not better, outcomes than the traditional classroom setting ($M=639$). (Newberry, 2015).

Outside the academic setting, other professional healthcare organizations, such as the American Heart Association (AHA), have had success in using hybrid learning modules to train learners. A professional can take the classroom learning section for Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), and Pediatric Advanced Life Support (PALS) through the AHA website and schedule the one-day skills portion with a licensed facility. The data supports the use of hybrid training for providers. This technology has great potential in future training and recruitment to expand the practice of Advance Practice Registered Nurses (APRNs), especially for those who have a busy schedule.

Conclusion

The Doctor of Nursing Practice- educated APRNs are uniquely prepared and positioned to close the gap between discovery of new knowledge and dissemination - translating evidence and integrating the evidence into practice. The evidence provided in this paper validates the seriousness of CCHDs and the benefits, as well as the effectiveness, of implementing the screen in practice. The purpose of the proposed project was designed with this evidence to enhance midwifery practice and health outcomes of their clients/newborns through the implementation of the CCHD screen in homebirths. The inability to complete this project as it was initially conceived increased my appreciation for the amount of time, effort, and communication that was needed. However, the beginning pieces of the project are intact. There are many challenges when engaging active practices. For future implementation attempts it may be more beneficial to implement the module and training in partnership with a midwifery school, moving the education upstream, so future midwives will be trained in the CCHD screen. In this way, midwives who participate in homebirths would anticipate this need, rather than have to retrofit their practices. The hybrid training module may also be of use in schools who have distance students. In the end, what I now know is that regardless of which group is recruited for the CCHD training, students or practicing midwives, it is important to find ways to implement this potentially lifesaving screen in what is currently an overlooked population.

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Appendix A

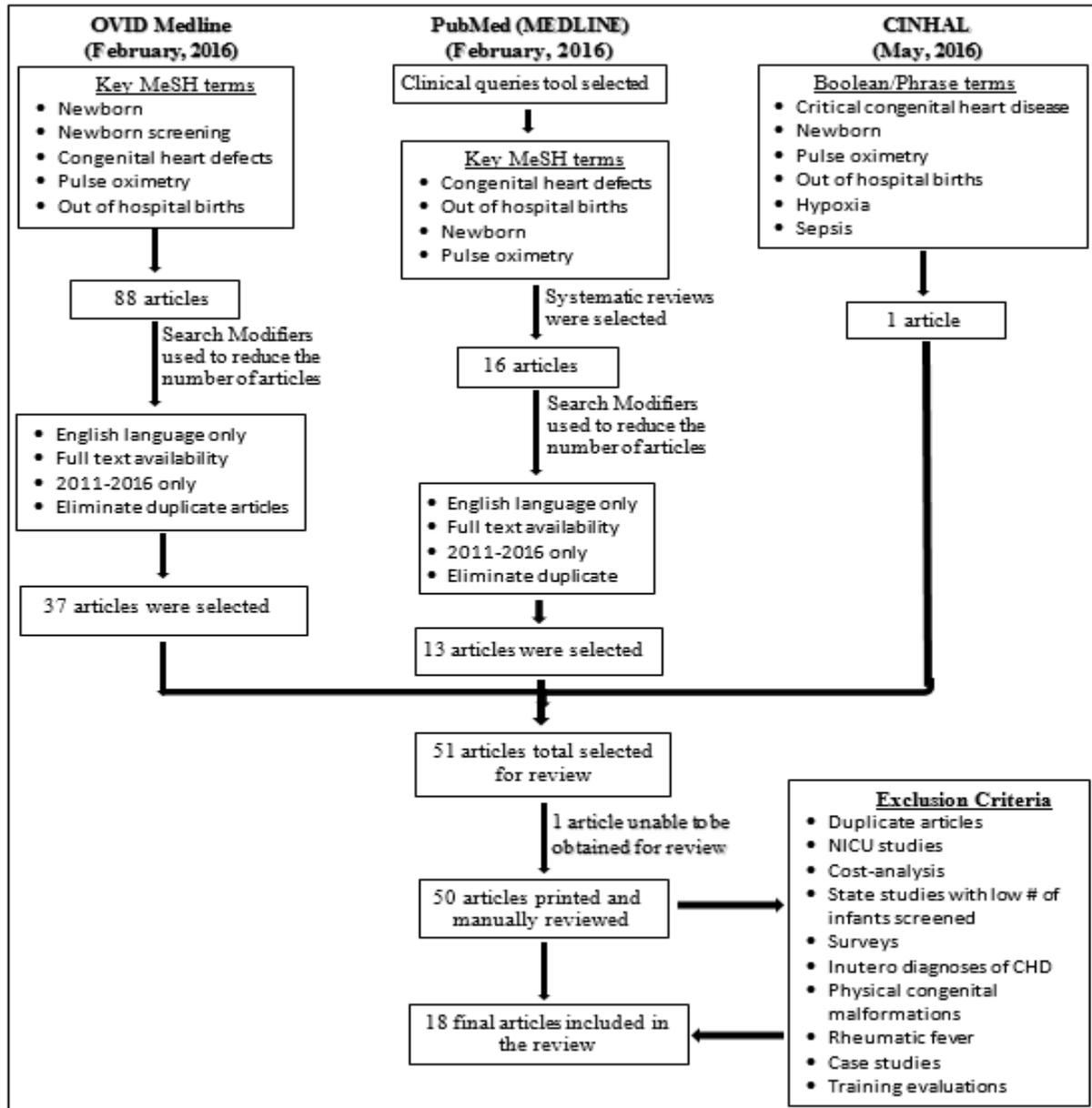
Total Live Births and Homebirths in Oregon 2010-2015 from Oregon Health Authority (2016)

Table A1

Year	Total Live Births	Total Newborns Delivered via Planned Homebirths
2010	45,904	965
2011	45,485	987
2012	45,566	1,022
2013	45,591	984
2014	46,100	1,060
2015	46,092	905

Appendix B
Detailed Database Search Method

Figure A1



*Ovid MEDLINE databases accessed: Ovid MEDLINE(R) 1946 to February Week 2 2016, Health and Psychosocial Instruments 1985 to January 2016, Ovid Healthstar 1966 to November 2015, EBM Reviews - Cochrane Database of Systematic Reviews 2005 to February 19, 2016, EBM Reviews - ACP Journal Club 1991 to February 2016, EBM Reviews - Cochrane Central Register of Controlled Trials January 2016, EBM Reviews - Cochrane Methodology Register 3rd Quarter 2012, EBM Reviews - Health Technology Assessment 1st Quarter 2016

Appendix C
Design Categorization of Literature Review of Pulse Oximetry in CCHD Screening

Table A2

Author & Date	Design	Sample, Sample Size, & Setting	Additional information
Ailes, Gilboa, Honein, & Oster, 2015	Research Support, U.S. Gov't, P.H.S Quantitative non-experimental predictive design study	□ n/a	United States
Amsbaugh, Scott, Shannon, & Foss, 2015	Research Support, Non-U.S. Gov't Meta-analysis	□ n/a	
Bradshaw & Martin, 2012	Review CPG	□ n/a	
Crouch, Speroni, Jones, MaDougall, & Daniel, 2016	Prospective descriptive research study	Rural, mid-Atlantic, 13 bed, level 1 hospital 1,002 Newborns >35wks gestation	United States
Ewer, 2014	Review CPG	□ n/a	
Ewer, 2013a	Review CPG	□ n/a	
Ewer, 2013b	Systematic Review and meta-analysis	13 studies, 230,00 newborns	
Ewer et al, 2012	Test accuracy study	□ n/a	
Ewer et al., 2011	Systematic review	6 maternity units in the UK, 20,055 asymptomatic newborn >34wks gestation	United Kingdom
Fillips & Bucciarelli, 2015	Systematic Review & meta-analysis	13 studies, 230,000 newborns	
Harold, 2014	CPG	□ n/a	
Hoffman, 2011	Meta-analysis	□ n/a	
Lhost et al., 2014	Observational study	11 month study of non-hospital births 449 newborns	Wisconsin, United States SHINE Project
Mellander, 2013	Research Support, Non-U.S. Gov't Review CPG	□ n/a	

Oakley et al., 2014	Prospective screening study	Single institution, 6,329 asymptomatic newborns >35 wks gestation	United Kingdom
Pflugeisen et al., 2015	Research Support, Non-U.S. Gov't Time Series Analysis	Review of 6 years of screening data 18,363 newborns	United States
Plana et al., 2015	Protocol Systematic review	□ n/a	United States
Thangaratinam et al., 2012	Systematic review & meta-analysis	Screened 552 studies, identified 13 eligible studies with data for 229,421 newborns	

Appendix D

Summary of Recent Large Population-based Studies of Newborn Pulse Oximetry Screening Using Pre- and Post-ductal Measurements (Published Since the 2009 AHA/AAP Scientific Statement)

Table A3

Author	No. of NBs	Sensitivity	Specificity	False Positive Rate
de-Wahl <u>Granelli</u> et al., (2009)	39,821	62%	99.8%	0.17%
<u>Riede</u> et al., (2010)	41,445	77.8%	99.9%	0.10%
Ewer et al., (2011)	20,055	75%	99.1%	0.84%
Oakley et al., (2014)	6,329	87.5%	99.8%	0.29%

Appendix E
CCHD Screening Results for Wisconsin SHINE Project (2013)

Table A4

Data Collected Over 11 Months

449 Infants screened

3 failed screen

- 1 CHD
- 2 Sepsis

5 screens that were a result of misinterpreting the algorithm

1 false negative

Appendix F
Purposed Data Collection Suggested by 2016 AAP Guidelines

Table A5

Age of the neonate at the time of screening
Specific values of each oximetry result, including the site from which it was obtained, and if it was deemed a pass or fail
If screen was not completed document reason
Subsequent activities related to a failed screen with specific diagnosis
