

Newborn Pulse Oximetry Screening to Detect Critical Congenital Heart Disease

Matthew A. Studer, MD¹, Ashley E. Smith, MD¹, Michael B. Lustik², and Michael R. Carr, MD³

Objectives To describe current practice and clarify provider opinion in the US with regard to newborn pulse oximetry screening (NPOx) for critical congenital heart disease.

Study design An internet-based questionnaire was forwarded to general pediatricians, neonatologists, and family medicine physicians. Physicians were surveyed regarding involvement in newborn medicine, knowledge of NPOx recommendations, and opinions regarding screening. NPOx protocol specifics were also queried.

Results Survey responses (n = 481) were received with 349 respondents involved in newborn medicine. Forty-nine percent (95% CI 44%-54%) of those involved in newborn medicine practice at a hospital with a NPOx protocol. Sixty-six percent of providers endorsed it as an effective tool, 20% required more education, 11% questioned its sensitivity, and 3% had no opinion. Sixty-five percent of providers were aware of recent state legislation mandating its use and 46% reported awareness of the addition of NPOx to the Recommended Uniform Screening Panel. Eighty-four percent of providers who practice at a hospital without a NPOx protocol were interested in its implementation. NPOx protocols varied and were not uniform with differences in time of test, location of probe, and values considered positive.

Conclusions NPOx has grown in its prevalence and acceptance in clinical practice, yet is far from universal in its application and design despite the recent American Academy of Pediatrics endorsement and its addition to the Recommended Uniform Screening Panel. The majority of physicians involved in newborn medicine deemed it an effective tool. (*J Pediatr* 2014;164:505-9).

Critical congenital heart disease accounts for approximately 10%-15% of all forms of congenital heart disease (frequency of ~1.2-1.7 per 1000 live births) and is defined as cardiac conditions that would require surgery or a catheter-based intervention in the first few weeks of life.¹⁻³ Delays in the identification of infants born with ductal-dependent critical congenital heart disease have been reported to occur in 20%-25% of infants with 1 study identifying 43% of those infants presenting in shock after having been discharged from the newborn nursery, and another reporting 5% identified at autopsy.⁴⁻⁶ Conversely, early diagnosis with timely surgical intervention has been shown to improve outcomes.^{7,8} To that end, the challenge of early diagnosis primarily falls to general practitioners who have historically relied on the physical examination to detect critical congenital heart disease. However, a large percentage of infants do not present with murmurs, vital sign abnormalities, or obvious cyanosis in the immediate postnatal period, resulting in missed diagnoses.⁹⁻¹² In an effort to improve detection of asymptomatic infants born with critical congenital heart disease, pulse oximetry screening (POx) in the newborn nursery has been proposed with the benefit and feasibility of its use well reported in the literature.¹³⁻¹⁸

Universal newborn pulse oximetry screening (NPOx) to detect critical congenital heart disease was added to the Recommended Uniform Screening Panel (RUSP) by the Health and Human Services Secretary in September 2011.¹⁹ It has also been endorsed by the American Academy of Pediatrics, American Heart Association, American College of Cardiology, and the March of Dimes.²⁰⁻²² And finally, a number of states have approved or proposed legislation surrounding its use with New Jersey being the first state to implement legislatively mandated POx in June 2011.^{23,24} Despite these recommendations and state legislation, details about current use of NPOx nationwide and provider opinions regarding this practice remain limited.

The aim of this study was to describe current practice and clarify provider opinion in the US with regard to NPOx for critical congenital heart disease.

Methods

Healthcare providers involved in newborn medicine were the targeted demographic. An internet-based questionnaire was forwarded to 5000 providers, including general pediatricians (3500), neonatologists (750), and family medicine

NPOx	Newborn pulse oximetry screening
POx	Pulse oximetry screening
RUSP	Recommended Uniform Screening Panel

From the Departments of ¹Pediatrics and ²Clinical Investigation, Tripler Army Medical Center, Honolulu, HI; and ³Department of Pediatrics, Pediatric Cardiology, Ann and Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, IL

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physicians (750) across all regions of the US (Appendix; available at www.jpeds.com). A reminder e-mail was sent 3 weeks after the original e-mail. The majority of responses were collected from February through May of 2012.

The study protocol was approved by the Human Use Committee at Tripler Army Medical Center. Investigators adhered to the policies for protection of human subjects as prescribed in 45 Code of Federal Regulation 46.

Providers were identified utilizing the American Medical Association Masterfile Database. This is a database of >900 000 physicians in the US of all specialties. Providers selected were done so at random though provider specialties, and other unique identifiers were intentionally chosen in an effort to identify the greatest number of providers involved in newborn medicine. The distribution of providers was intentionally weighted toward general pediatricians, but included neonatologists and family medicine providers in an effort to provide a representative sample of each specialty involved in newborn medicine. Participation in newborn medicine itself was not an identifier in the database. We requested a representative sample of providers from all regions of the US, but did not specifically inquire about region of practice in the questionnaire. Only physicians involved in newborn medicine were included in the analysis.

Physicians were surveyed regarding involvement in newborn medicine, demographic data, knowledge of POx recommendations, and opinions regarding this screening technique. Questions pertaining to the use of NPOx and specifics of the protocol were posed. If a provider did not practice at a hospital with POx they were asked about their interest in initiating this screening tool along with any perceived barriers to its implementation. If a provider practiced at more than 1 hospital or specified a hospital setting not included in the primary list, the site of their primary hospital location or the hospital size which was closest in similarity was chosen. Providers who omitted a question were not included in the analysis of that particular question.

Descriptive data were reported using percentages. Group responses were compared using the Fisher exact test or chi-square test as applicable. Statistical significance was determined by a *P* value <.05. When applicable, 95% CI were included. Results are unweighted and not adjusted for sampling fractions because of unknown population totals for the provider types. Statistical analysis was performed with SAS software v. 9.2 for Windows (SAS Institute Inc, Cary, North Carolina).

Results

Four hundred eighty-one total survey responses were received for an overall response rate of 10% (9% for general pediatricians, 18% for neonatologists, and 2% for family medicine). Nearly three-fourths of respondents were involved in newborn medicine (*n* = 349, 73%), and of those, 238 were general pediatricians (68%), 100 were neonatologists (29%), 10 were family practitioners (3%), and 1 did not specify (Table I).

Table I. Responses from providers involved in NBM

	Respondents
Involvement in NBM	
Total respondents	<i>n</i> = 349
General pediatricians	238 (68%)
Neonatologists	100 (29%)
Family medicine	10 (3%)
NPOx protocol—yes	<i>n</i> = 171 (49%)
Hospital setting of practice	
Large urban	44%
Small urban	23%
Academic	20%
Rural	13%
Opinion of NPOx	
Effective	66%
More education	20%
Not sensitive	11%
No opinion	3%
Aware of state legislation	65%
Aware of addition to RUSP	46%

NBM, newborn medicine.

Approximately one-half of the respondents involved in newborn medicine currently practice at a hospital with a NPOx protocol in place (49%, 95% CI 44%-54%). Providers were polled about the hospital setting in which they practice. Most respondents practiced at a hospital in a large urban setting (44%), followed by small urban setting (23%), academic (20%), and rural (13%).

Opinions regarding NPOx varied, with 66% of all respondents endorsing it as an effective tool, 20% requiring more education, 11% believing that the screen was not sensitive enough, and 3% with no opinion. Providers' knowledge of recent recommendations was also assessed. Nearly two-thirds of providers involved in newborn medicine were aware of recent state legislation mandating its use (65%), but less than one-half reported awareness of the addition of POx to the RUSP (46%).

Providers without a pulse oximetry protocol were queried further regarding their thoughts about the ease of implementing a pulse oximetry protocol as well as any barriers they felt might make it more challenging. Nearly 60% of these providers believed implementation would be 'easy' (56%, 95% CI 49%-64%). The most common barriers cited included follow-up of positive tests (53%), inaccurate recordings (48%), and training challenges (44%). Regardless of perceptions about ease of implementation and the perceived barriers, 84% were interested in implementing a POx protocol.

The distribution of opinions and knowledge of guidelines differed significantly depending on whether or not the provider practiced at a hospital where POx was already established (Table II). Providers practicing at a hospital with an established POx protocol were more likely to consider it effective than providers at hospitals without a protocol in place (84% vs 52%, *P* < .001). Providers practicing at a hospital with an established protocol were also less likely to require education (8% vs 29%, *P* < .001) and less likely to question the sensitivity of the test (5% vs 16%, *P* = .002). They were also more likely to report knowledge of state

Table II. Comparisons between providers who practice at a hospital with vs hospital without a NPOx protocol

	All respondents involved in NBM	Hospital w/ NPOx protocol	Hospital w/o NPOx protocol	P value
Opinion of NPOx				
Effective	66%	84%	52%	<.001
More education	20%	8%	29%	<.001
Not sensitive	11%	5%	16%	.002
No opinion	3%	3%	3%	1.000
Aware of state legislation	65%	74%	58%	<.01
Aware of addition to RUSP	46%	55%	39%	<.01

legislation (74% vs 58%, $P < .01$) and the RUSP guidelines (55% vs 39%, $P < .01$).

Hospital setting did not predict the use of screening pulse oximetry ($P = .26$) with a fairly equal distribution of those with a protocol among the various hospital types. Furthermore, the distribution of providers' opinions toward pulse oximetry testing did not differ comparing responses based upon the hospital setting in which they practice ($P = .25$).

Responses from general pediatricians and neonatologists were analyzed individually (Table III). Neonatologists were more likely than general pediatricians to practice in a setting with a discharge protocol in place, but the difference was not significant (56% vs 46%, $P = 0.121$). There was no difference between provider types regarding opinion toward POx with an equal distribution of those who felt the screening protocol was an effective tool ($P = .8$), those who needed more education ($P = .548$), those who deemed it not sensitive enough ($P = .440$), and those without an opinion ($P = .459$). Neonatologists were more likely than general pediatricians to be aware of both state legislation mandating screening (86% vs 57%, $P < .001$) and the recent addition of screening guidelines to the RUSP (78% vs 34%, $P < .001$). Finally, among providers at hospitals with no protocol in place, although pediatricians were more likely than neonatologists to believe that implementation of a screening protocol would be easy (61% vs 45%, $P = .001$), potential barriers to implementation did not differ between the 2 groups.

Providers who practice at a hospital with a pulse oximetry protocol were asked about details of their protocol, including

Table III. Comparisons between general pediatricians vs neonatologists regarding POx protocols

	General pediatricians	Neonatologists	P value
NPOx protocol	46%	56%	.121
Opinion of NPOx screening			
Effective	68%	66%	.800
More education	20%	17%	.548
Not sensitive	10%	13%	.440
No opinion	2%	4%	.459
Aware of state legislation	57%	86%	<.001
Aware of addition to RUSP	34%	78%	<.001
Implementation "easy"	61%	45%	.01

timing of screening, location of the pulse oximetry probe, and the value considered to be a positive test (Figure). The majority of respondents stated that their protocol tested at >24 hours of life (83%), though some variability or uncertainty was shared. Sixty-three percent of respondents test with a probe on both the hand and foot, 19% test only the foot, 7% only the hand, and 11% did not specify. Most consider a value <95% to be a positive test (59%), but there was also a significant degree of variability in this metric with 16% using a value <90%, 3% using a value <98%, and 4% using an "other" value not included in the survey question. Eighteen percent of respondents were unsure of the value used in their protocol to signify a positive test.

Over 40% of respondents had free-text comments at the end of the survey. Twelve percent stated that protocol implementation or planning was in progress at their institution.

Discussion

In September 2011, the Health and Human Services Secretary added universal screening discharge pulse oximetry to the RUSP in an effort to better identify asymptomatic infants with critical congenital heart disease prior to discharge from the newborn nursery.¹⁹ At the time of our survey, one-half of the respondents involved in newborn medicine practiced at a hospital utilizing formal POx in their newborn nursery. This percentage, though far from universal, is notably higher than our previous study of military hospitals in 2009 and the Wisconsin and Georgia studies in 2011 and 2012, respectively.²⁵⁻²⁷

The majority of physicians involved in newborn medicine deemed it an effective tool, indicating that many feel it has an important role in clinical practice. As one might expect, providers with established protocols were more comfortable with the protocol specifics and were less likely to require additional education. Furthermore, of those who practice without a protocol, the majority was interested in implementing a protocol and felt implementation would be "easy." This would indicate that previously described barriers, such as low sensitivity, reliability of testing, education, referral issues, and cost,^{17,28-30} which were also notable concerns in our survey, though relevant, are not necessarily overwhelming impediments to implementation. There remains, however, a need for further instruction for providers about this screening protocol as evidenced by the number of respondents who felt they required more education.

Two-thirds of neonatologists and general pediatricians felt that POx was an effective tool. This is nearly identical to the 64% of pediatric cardiologists surveyed in 2009 who reported that POx was effective in detecting ductal-dependent lesions and cyanotic congenital heart disease.³¹ Though the sensitivity of POx was questioned by a slightly higher number of neonatologists and a call for more education requested by general pediatricians, neither approached statistical significance of pre-existing institutional impediments in terms of establishing this type of protocol.

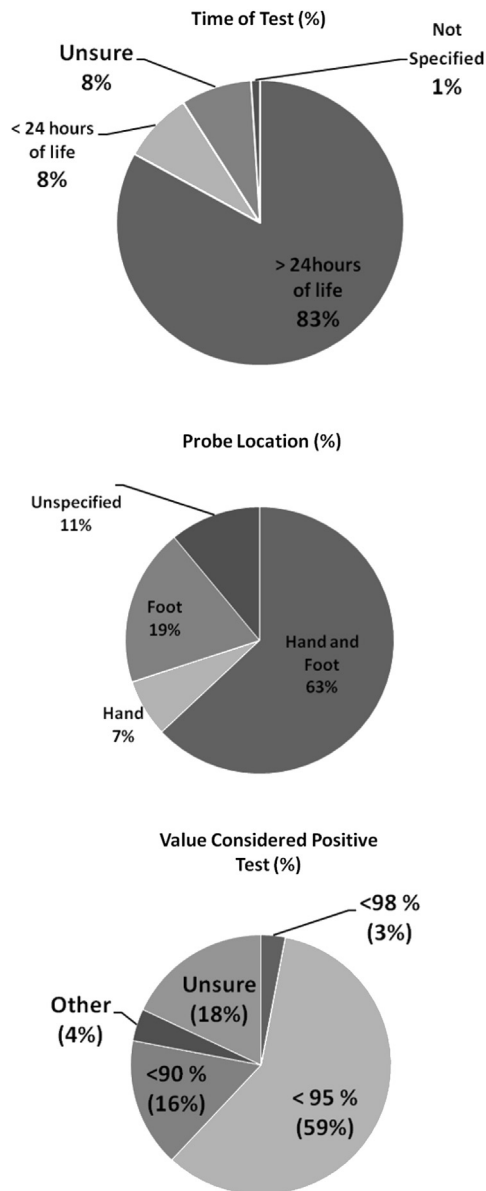


Figure. Summary of pulse oximetry protocol specifics.

At the present time, there does not appear to be a hospital demographic in which POx is more commonly practiced. The survey did not clarify the resources of respective hospitals and only queried providers about the primary hospital in which they practice, but it would appear that neither practice at a rural hospital, conceivably without readily available subspecialty services, nor practice at an academic center with improved availability and possibly even onsite consultation with pediatric cardiologists, predicted use of POx.

The American Academy of Pediatrics' endorsement recommends that screening should target all healthy newborns and be performed in a standardized fashion.^{17,20,21} This survey provides details about current protocol specifics, demonstrating that nationally they are not yet fully uniform with

notable variation in aspects of the screening process. Specifically, the value below which should be considered a positive test, extremity to test (hand vs foot vs both), and timing of the test were inconsistent. However, most did mirror the recently published American Academy of Pediatrics guidelines.³²

Of the 40% of respondents who had free-text comments at the end of the survey, 12% stated that protocol implementation or planning was in progress at their institution. Data from the state of Georgia mirrored this trend as 28% of hospitals in the state had plans for pulse oximetry testing in 2012.²⁷ This further confirms the growing number of hospitals adopting this new addition to the RUSP. Most comments were in support of the effectiveness of this screening tool, however, some vehemently opposed the screen as unnecessary. We believe that the large number of free-text comments speaks to the growing awareness of, interest in, and controversies surrounding NPOx, all of which are expected when an endeavor on such a national scale takes place.

A few key limitations to this study should be addressed. The overall response rate was 10% and although an adequate number of responses were received to perform statistical analysis, our overall results may not reflect those of the non-respondents or the nation as a whole. The percent of non-response was likely secondary to the lack of a clear demographic in the Masterfile Database that specified involvement in newborn medicine. This may have resulted in a large percentage of surveys being sent to providers not involved with the issue of pulse oximetry testing. A second limitation of this study relates to the greater percentage of responses from neonatologists and minimal response from family medicine providers. As such, our results, which were unweighted, may be biased by this oversampling of neonatologists and undersampling of family medicine providers. Third, our survey did not include questions detailing the region of practice or exact hospital in which a provider practiced. To that end, we are unable to comment on regional variations in opinion and practice and, in theory, could have had multiple providers from a single hospital respond to our survey, thus confounding some of our data and statistical interpretation.

We recognize that this is a fluid time in the implementation of POx. At the time of this submission, 30 states have signed legislation endorsing and/or mandating its use though variations in the specific details of the states' respective legislation are widespread with "legislation" not necessarily equating to mandatory screening. Three states have regulatory additions, 2 states have legislation proposed, 6 states have pilot projects but no legislation, and 9 states have no legislative action.²³ As referenced in the free-text comments of our survey, a number of providers stated that they were in the process of implementing POx. With heightened national awareness and states' mandating POx, the number of providers who practice at a hospital which has adopted POx is likely greater than the 49% reported here.

Our hope is that these data will assist providers, hospitals, advocacy groups, and state legislatures in the debate surrounding the routine use of NPOx and its application in the US. A great majority of providers are interested in this

screening protocol, but many theoretical and real challenges remain before this is truly a widely implemented and sustainable endeavor. ■

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Reprint requests: Matthew A. Studer, MD, Department of Pediatrics, Tripler Army Medical Center, 1 Jarrett White Road, Honolulu, HI 96859. E-mail: matthew.a.studer.mil@mail.mil

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- 1) Please specify your specialty of training
 - a. General pediatrics
 - b. Family medicine
 - c. Neonatology
 - d. Other
- 2) What is your opinion regarding universal application of a discharge screening pulse oximetry protocol to screen asymptomatic newborn infants for congenital heart disease?
 - a. Effective screening tool to detect cyanotic congenital heart disease
 - b. Not sensitive enough to warrant the time and effort of such a protocol
 - c. I need more education about the efficacy of this screening test
 - d. No opinion
- 3) Are you aware that some states have passed legislation, or are considering legislation, mandating screening discharge pulse oximetry for all newborn infants prior to discharge home?
 - a. Yes, I was aware
 - b. No, I was not aware
- 4) Are you aware that the Secretary of Health and Human Services has agreed to the addition of screening discharge pulse oximetry to the Recommended Uniform Screening Panel?
 - a. Yes, I was aware
 - b. No, I was not aware
- 5) Are you directly involved in the newborn nursery care and discharge of healthy term infants?
 - a. Yes
 - b. No (If no, you need not answer the remaining questions in our survey. Thank you.)
- 6) In general, how would you describe the location of the newborn nursery in which you primarily work?
 - a. Academic/University Hospital
 - b. Large urban community hospital (>200 deliveries per month)
 - c. Small urban community hospital (<200 deliveries per month)
 - d. Rural hospital setting
 - e. Other (please describe)
- 7) At your primary hospital, does the nursery have in place a discharge screening pulse oximetry protocol to screen asymptomatic newborn infants for cyanotic congenital heart disease?
 - a. Yes (Please skip to question 11)
 - b. No

Appendix. Survey questions and answers. (*Continues*)

- 8) If your primary hospital does NOT have a discharge screening pulse oximetry protocol, how difficult do you feel it would be to implement?
- Easy
 - Difficult
 - Impossible
 - No opinion
- 9) If difficult or impossible, please explain why (select all that apply)?
- Training challenges
 - Lack of available subspecialty services
 - Inadequate staffing
 - Inaccurate recordings
 - Financial constraints
 - What to do with a positive test?
 - Other (please describe below)
- 10) If your primary hospital does NOT have a discharge screening pulse oximetry protocol, are you interested in implementing one?
- Yes
 - No
- 11) If your primary hospital DOES have a discharge screening pulse oximetry protocol, can you recall the time when the test is performed?
- Less than 24 hours of life
 - More than 24 hours of life
 - Not specified in our protocol
 - I am unsure
- 12) If your primary hospital DOES have a discharge screening pulse oximetry protocol, can you recall the location where the pulse oximetry probe is placed?
- Hand
 - Foot
 - Both hand and foot
 - Not specified in our protocol
- 13) If your primary hospital DOES have a discharge pulse oximetry screening protocol, can you recall the value below which the screen is considered positive?
- Less than 98%
 - Less than 95%
 - Less than 90%
 - I am unsure
 - Other (please describe below)
- 14) Please use this final area to share with us any additional information you feel is pertinent to the universal application of a newborn discharge pulse oximetry screening protocol.

Appendix. Continued.
