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Current Postlaunch Implementation of State Mandates of Newborn Screening for Critical Congenital Heart Disease by Pulse Oximetry in U.S. States and Hospitals

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Abstract

Objective Our objective was to gauge adherence to nationally endorsed protocols in implementation of pulse oximetry (POx) screening for critical congenital heart disease (CCHD) in infants after mandate by all states and to assess associated characteristics.

Study Design Between March and October 2019, an online questionnaire was administered to nurse supervisors who oversee personnel conducting POx screening. The questionnaire used eight questions regarding performance and interpretation of screening protocols to measure policy consistency, which is adherence to nationally endorsed protocols for POx screening developed by professional medical societies. Multilevel linear regression models evaluated associations between policy consistency and characteristics of hospitals and individuals, state of hospital location, early versus late mandate adopters, and state reporting requirements.

Results Responses from 189 nurse supervisors spanning 38 states were analyzed. Only 17% received maximum points indicating full policy consistency, and 24% selected

Keywords

- RUSP
- pulse oximetry screening
- CFIR
- implementation
- newborn screening
- CCHD
- congenital heart disease
- United States
- nurses

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all four options for potential hypoxia that require a repeat screen. Notably, 33% did not recognize ≤90% SpO_2 as an immediate failed screen and 31% responded that an infant with SpO_2 of 89% in one extremity will be rescreened by nurses in an hour rather than receiving an immediate physician referral. Lower policy consistency was associated with lack of state reporting mandates (beta = −1.23 $p = 0.01$) and early adoption by states (beta = −1.01, $p < 0.01$).

Conclusion When presented with SpO_2 screening values on a questionnaire, a low percentage of nurse supervisors selected responses that demonstrated adherence to nationally endorsed protocols for CCHD screening. Most notably, almost one-third of respondents did not recognize ≤90% SpO_2 as a failed screen that requires immediate physician follow-up. In addition, states without reporting mandates and early adopter states were associated with low policy consistency. Implementing state reporting requirements might increase policy consistency, but some inconsistency may be the result of unique protocols in early adopter states that differ from nationally endorsed protocols.

Key Points

- Low adherence to nationally endorsed protocols.
- Inconsistent physician follow-up to hypoxia.
- Reporting improved consistency with national policy.

Newborn screening with the U.S. Recommended Uniform Screening Panel (RUSP) is an essential public health responsibility performed by hospital nursery personnel to reduce morbidity and mortality from infant heritable disorders.[1] RUSP screenings are highly efficacious protocols endorsed at the national level.[1] However, poor or incorrect implementation and missed screenings can create disparities affecting health outcomes in infants.

Screening for critical congenital heart disease (CCHD) using pulse oximetry (POx screening) was added to the RUSP in 2011 by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children of the Health Resources and Services Administration.[2–4] Professional and nonprofit health societies, such as the American Academy of Pediatrics (AAP), collaborated to endorse specific evidence-based operational protocols for screening. CCHD is defined as life-threatening structural malformations of the heart requiring surgery or catheter-based intervention before the age of 1 year.[5] With CCHD affecting approximately 7,200 newborns a year in the United States, early detection before postnatal discharge significantly lowers mortality risk.[6] CCHD causes about 2,734 deaths (2007–2013) per year,[7] as well as neurodevelopmental dysfunction,[8,9] and behavioral and psychosocial issues.[10–14] Approximately one-quarter of newborns with CCHD were discharged undiagnosed from hospitals before infant screening using POx began in 2011.[15,16]

A pulse oximeter is a device that can measure lower-than-normal oxygen saturations simply and very inexpensively.[17,18] POx screening has moderate sensitivity (76.3%), high specificity (99.9%), and a low false-positive rate (0.14%)[19] in detecting cyanotic conditions like CCHD. As a point-of-care screening, results are received instantaneously.[17]

Physicians, nurses, parents, medical associations, and newborn screening interest groups worked together to successfully advocate for state laws requiring CCHD screening with POx. By 2018, all 50 states and the District of Columbia (DC) had implemented screening mandates. Despite productive efforts to develop a national approach to CCHD screening,[20] some state and hospital-level variations exist regarding training standards, reporting requirements, and the algorithm used to perform the screening. Guidelines for POx screening approved by the AAP[21] will be referred to as nationally endorsed protocols.[3,20] According to compiled state legislative and regulatory data, only 10 states require the use of nationally endorsed protocols, with another 16 states referencing the protocols in training, but not specifically requiring their use. The other 24 states mandate screening but do not specify required protocols.

An expert panel met in September 2018 and recommended modifications to the current nationally endorsed protocols. Recommendations include changing the passing oxygen saturation threshold to at least 95% in both the upper and lower extremities, rather than just one extremity, and eliminating the second repeat screen.[21] However, the recommendations were not published in a peer-reviewed journal until several months after completion of our survey study and have yet to be endorsed by the AAP. Therefore, it is unlikely that hospitals had modified their protocols to reflect the recommended changes at the time of our survey.

Postlaunch implementation of screening within the RUSP calls for monitoring, periodic evaluation, and improvements. This study evaluated how CCHD screening with POx is currently being practiced in hospitals. In addition to assessing implementation levels, this paper investigated the association of characteristics of individuals, organizations, and settings with adherence to nationally endorsed protocols for POx screening.

Materials and Methods

An online questionnaire was developed to determine the implementation status of POx screening. To structure our study and design the questionnaire, the Consolidated Framework for Implementation Research (CFIR), a conceptual model developed by Damschroder et al,[22] was employed. CFIR has five domains associated with intervention implementation: (1) intervention characteristics; (2) inner setting (internal influences, individuals, locations, etc.); (3) outer setting (significant external influences, authorities, locations, etc.); (4) individuals involved; and (5) implementation (or execution) process.[22] POx screening is the intervention for CCHD (domain no. 1). Responses reflected access to information and knowledge (subconstruct of domain no. 4) as provided by the state and hospital in policy updates and training.[22] Questionnaire development was a collaborative effort between the study team and health care professionals.

For simplicity, policy consistency was defined in this study as the level of adherence to nationally endorsed protocols of POx screening observed from questionnaire responses. Assessing policy consistency can help identify barriers and facilitators to achieving appropriate implementation of POx postlaunch, so effective modifications can be made in the postlaunch maintenance stage.

Nurses overseeing personnel who perform POx screening for infants in well-baby nurseries, which included nurse managers, directors of nursing, clinical nurse specialists, registered nurses, and midwives, hereafter referred to as nurse supervisors, were targeted for the survey. The questionnaire was pilot tested with 29 nurse supervisors at nearby hospitals who were excluded from the main study.

Between March 2019 and October 2019, the questionnaire was administered to nurse supervisors in 38 states. A recruitment invitation was disseminated by email through different organizations to recruit nurse supervisors from a diverse pool of medical centers and hospitals from urban, suburban, and rural locales. State point persons from NewSTEPs[23] and Baby's First Test[24] were enlisted, as well as directors of the Regional Prenatal Program of California. Several point persons forwarded invitation emails to hospitals or provided contacts within their regions or states. Birthing hospitals were identified through websites[25–32] to "cold-call" for contacts. A member of the Well Newborn Special Interest Group (SIG) of the Academic Pediatric Association also forwarded the invitation email through SIG's listserv.

Information sheets with study aims and questionnaire links were sent via email on a rolling basis using a snowball sampling method to encourage participants to forward the email to appropriate coworkers and staff. Respondents from hospitals not performing POx screening or those not supervising employees performing POx screening were excluded from the analyses.

Questions were included to assess POx screening protocol characteristics, nursing supervisor characteristics, and hospital characteristics including ownership, metropolitan location, racial and ethnic demographics of patients, number of deliveries, teaching status, municipal environment of hospital, and state in which the hospital is located.

In addition, eight questions on screening protocol were included in the questionnaire to develop a policy consistency score. The questions aimed to reveal what nurse supervisors considered the correct course of action in POx screening and interpretation of screening results based on hospital protocols, given that implementation and protocol laws and requirements vary by state. (The questionnaire is provided in ►**Supplementary Table S1**; available in the online version). Thus, scoring for the hospital policy consistency served as a proxy for the status of POx screening implementation level.

Statistical Analyses

Multilevel linear regression models were used to evaluate associations between policy consistency and the predictors listed below. State random effects were included to account for residual correlations, as well as the effect on standard errors of estimates and *p*-values for clustering within states.

Policy consistency for implementation of POx screening was scored based on responses to the eight protocol questions listed in ►**Supplementary Table S1** (available in the online version). Some questions assessed knowledge of screening timeframe, and others, marginal oxygen saturation or values requiring a "fail." Another question determined under what circumstances a nurse would contact a physician to evaluate the cause of suspected hypoxia.

A maximum score of 10 points represented hospital *policy consistency* as the primary outcome. Answers corresponding to *policy consistency* questions earned one point. Two "select all that apply" questions (#16 and #18) earned an extra point for multiple-compliant responses. For screening timeframe (#13), either of the two compliant options earned a maximum of one point. ►**Table 1** contains descriptive statistics of questionnaire responses, and ►**Tables 2** and **3** show point allocations. Internal consistency reliability of the total score was estimated using coefficient alpha.[33]

Characteristics used as predictor variables included the job title of the respondent (nurse manager or director of nursing, clinical nurse specialist or registered nurse [RN], and other), hospital teaching status, location of hospital (metropolitan area or other, and national region), ownership (private or public), number of newborn deliveries (an estimate stratified as small, medium, and large nursery), and predominant, primary, and secondary race/ethnicity of the hospital's patients. For hospital ownership status (private or public) and primary race/ethnicity of the patient population,

Table 1 Descriptive statistics for hospitals and individual characteristics

	Total		Total point quartiles							
	Total		First (lowest quartile)		Second		Third		Fourth (highest quartile)	
	(*n* = 189)		(*n* = 46)		(*n* = 47)		(*n* = 31)		(*n* = 65)	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Q1 In which region is your hospital?										
Northeast Region	22	12	7	15	2	4	5	16	8	12
South	78	41	24	52	19	40	13	42	22	34
Midwest	38	20	5	11	13	28	5	16	15	23
West	51	27	10	22	13	28	8	26	20	31
Early vs. late adopters of the mandatory screening protocol[a]										
Early (2012 and 2013)	118	62	34	74	32	68	20	65	32	49
Late (2014–2018)	71	38	12	26	15	32	11	35	33	51
Q2 What is your job title?										
Nurse manager or director of nursing	114	60	25	54	34	72	19	61	36	55
Clinical nurse specialist or RN	34	18	11	24	8	17	6	19	9	14
Other	41	22	10	22	5	11	6	19	20	31
Q3 What is the teaching status of your hospital?										
Teaching	94	50	22	48	27	57	17	55	28	43
Nonteaching	85	45	22	48	18	38	11	35	34	52
I am not sure	10	5	2	4	2	4	3	10	3	5
Q4 Where is your hospital located?										
Metropolitan area	61	32	15	33	17	36	9	29	20	31
Nonmetropolitan area	124	66	30	65	29	62	21	68	44	68
I am not sure	4	2	1	2	1	2	1	3	1	2
Q5 Is the hospital private for-profit, private nonprofit, public, or other?										
Private	123	65	30	65	30	64	20	65	43	66
Public	61	32	14	30	16	34	10	32	21	32
Other	3	2	1	2	0	0	1	3	1	2
Missing	2	1	1	2	1	2	0	0	0	0
Q6 About how many newborn deliveries were there at your hospital in the last 12 months?										
Mean (SD)	1,592.36 (1,868.71)		1,795.35 (2,042.85)		1,447.49 (1,707.62)		1,779.68 (1,967.16)		1,464.12 (1,826.26)	
Median (IQR)	920 (325, 2,200)		935 (317, 2,800)		1,000 (318, 1,500)		1,079 (400, 2,200)		825 (300, 1,800)	
Q7 What best describes the racial/ethnic composition of the patients at your hospital?										
More than 90% of patients belong to one race/ethnic group	37	20	8	17	9	19	4	13	16	25
80–90% of patients belong to one race/ethnic group	52	28	11	24	13	28	8	26	20	31
Less than 80% of patients belong to one race/ethnic group	84	44	21	46	21	45	17	55	25	38
Skip this question	16	8	6	13	4	9	2	6	4	6

Table 1 (*Continued*)

	Total point quartiles									
	Total		First (lowest quartile)		Second		Third		Fourth (highest quartile)	
	(*n* = 189)		(*n* = 46)		(*n* = 47)		(*n* = 31)		(*n* = 65)	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Q7.1 What is the primary racial/ethnic group of the patients at your hospital?										
Non-Hispanic White	144	76	34	74	34	72	24	77	52	80
Non-Hispanic Black	8	4	2	4	3	6	2	6	1	2
Hispanic	15	8	2	4	5	11	2	6	6	9
Asian or Pacific Islander	3	2	0	0	1	2	1	3	1	2
Other	1	1	1	2	0	0	0	0	0	0
Missing	18	10	7	15	4	9	2	6	5	8
Q7.2 What is the secondary racial/ethnic group of the patients at your hospital?										
Non-Hispanic White	19	10	4	9	8	17	3	10	4	6
Non-Hispanic Black	46	24	10	22	10	21	7	23	19	29
Hispanic	54	29	11	24	12	26	12	39	19	29
Asian or Pacific Islander	6	3	1	2	4	9	0	0	1	2
Other	8	4	4	9	0	0	3	10	1	2
Missing	56	30	16	35	13	28	6	19	21	32
Q7.3 What is the tertiary racial/ethnic group of the patients at your hospital?										
Non-Hispanic White	9	5	4	9	2	4	1	3	2	3
Non-Hispanic Black	12	6	3	7	2	4	3	10	4	6
Hispanic	32	17	5	11	9	19	6	19	12	18
Asian or Pacific Islander	14	7	1	2	4	9	4	13	5	8
Other	13	7	7	15	2	4	3	10	1	2
Missing	109	58	26	57	28	60	14	45	41	63
Q11 Out of all the newborns eligible for CCHD screening at your hospital in the past year, about what percentage received the screening?										
Mean (SD)	99.13 (1.70)		99.27 (1.75)		98.87 (1.88)		99.45 (1.06)		99.06 (1.78)	
Median (IQR)	100 (99, 100)		100 (99, 100)		100 (98, 100)		100 (99,100)		100 (99, 100)	
Q12 What are your hospital's CCHD screening guidelines based on?										
Recommendations from the CDC/AAP (Kemper et al, 2011)	146	77	28	61	36	77	24	77	58	89
Recommendations from the state	111	59	29	63	26	55	16	52	40	62
Recommendations from the county	6	3	2	4	2	4	0	0	2	3
Published literature	69	37	14	30	16	34	6	19	33	51
The guidelines were developed at my own hospital	12	6	3	7	2	4	2	6	5	8
I don't know	5	3	3	7	1	2	0	0	1	2

Abbreviations: AAP, American Academy of Pediatrics; CCHD, critical congenital heart disease; CDC, Centers for Disease Control and Prevention; IQR, interquartile range; RN, registered nurse; SD, standard deviation.

[a]Early adopters were classified as states who implemented the recommended screening guidelines in 2012 or 2013. All states who implemented the recommended screening guidelines in 2014 or after were classified as late adopters

Table 2 Descriptive statistics for mechanics of the screening

	Total point quartiles									
	Total		First (lowest quartile)		Second		Third		Fourth (highest quartile)	
	(*n* = 189)		(*n* = 46)		(*n* = 47)		(*n* = 31)		(*n* = 65)	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Q13 When do the majority of infants at your hospital receive their screen?										
Less than 24 h after birth	1	1	1	2	0	0	0	0	0	0
At or around 24 h after birth (one point)	73	39	16	35	17	36	14	45	26	40
Between 24 h after birth and discharge (one point)	115	61	29	63	30	64	17	55	39	60
Any time before discharge	0	0	0	0	0	0	0	0	0	0
Q14 Where does your hospital place the pulse oximetry probe?										
Right hand and either foot (one point)	174	92	34	74	45	96	30	97	65	100
Left hand and either foot	4	2	3	7	1	2	0	0	0	0
Either hand or foot	2	1	2	4	0	0	0	0	0	0
Only right hand	2	1	2	4	0	0	0	0	0	0
Only left hand	0	0	0	0	0	0	0	0	0	0
Only right foot	3	2	1	2	1	2	1	3	0	0
Only left foot	0	0	0	0	0	0	0	0	0	0
I don't know	0	0	0	0	0	0	0	0	0	0
Missing	4	2	4	9	0	0	0	0	0	0

missing values were coded as "other." Hospitals that failed to report the number of deliveries were excluded.

Other predictor variables included timeframe of adoption of a statewide screening mandate and whether reporting of screening results to a state agency was required. For reporting of screening results, respondents also specified whether at least minimal documentation for number of infants screened was required. POx screening adoption was mandated by over half the states by 2014, so respondents from those states were considered early adopters. Respondents from states adopting POx screening between 2014 and 2018 were considered late adopters, as incrementally more implementation materials became available.

Seed Data for Qualitative Analysis

Questionnaire responses provided seed data for stage two, to develop interviews with nurse supervisors aimed at investigating barriers and facilitators to high implementation of POx screening. Periodic quantitative and qualitative assessments are necessary to develop improvements and reduce inequities in screening access and quality.[22]

Sensitivity Analyses

To evaluate the robustness of results, six sensitivity analyses were conducted. First, respondents were categorized into policy consistency quartiles based on total scores. Second and third, a composite index of policy consistency was created using principal component scores (rather than simple sums), with this same index used as a continuous value for the second sensitivity analysis and after categorizing into quartiles, for the third. Fourth, cases missing key information, such as hospital ownership or patient race/ethnicity, were excluded. Fifth, respondents unsure of teaching status, hospital location, and hospital ownership were excluded. Sixth, a point was credited to those individuals who indicated "I don't know."

The Institutional Review Board (IRB) at the Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center approved this study as "exempt" (IRB project number: 31224-01R).

SAS Version 9.4 PROC FACTOR was used to conduct principal component analyses (PCA). All other analyses were completed using Stata Version 14.2 (StataCorp LLC, College Station, TX).

Results

Questionnaires were completed from 38 states with no responses from 12 states or DC. Regions represented included northeast: 8; south: 13; midwest: 9; west: 8.[34] With 245 individuals responding and 56 excluded, a cohort of 189 nurse supervisors was assembled. Cohort exclusions (*n* = 56) included two individuals whose hospitals did not routinely screen for CCHD using POx, 20 individuals who did not

Table 3 Descriptive statistics for interpretation of the screening

	Total point quartiles									
	Total		First (lowest quartile)		Second		Third		Fourth (highest quartile)	
	(*n* = 189)		(*n* = 46)		(*n* = 47)		(*n* = 31)		(*n* = 65)	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Q15 Which of the following is considered an immediate FAIL on the first screen? (meaning screen is not repeated)										
A measure in which one of the extremities is less than 98%	1	1	1	2	0	0	0	0	0	0
A measure in which one of the extremities is less than 95%	26	14	9	20	6	13	5	16	6	9
A measure in which one of the extremities is less than 90% (one point)	127	67	11	24	30	64	25	81	61	94
A measure in which the difference in extremity measurements is greater than 3%, but otherwise in range	48	25	10	22%	20	43	7	23	11	17
I do not know	5	3	5	11	0	0	0	0	0	0
Other	18	10	8	17	4	9	3	10	3	5
Q16 For repeat screens, which of the following meet the criteria for a FAIL?										
A greater than 1% absolute difference exists between the hand and foot on three measures, each separated by 1 h	1	1	0	0	1	2	0	0	0	0
A greater than 3% absolute difference exists between the hand and foot on three measures, each separated by 20 min	17	9	11	24	4	9	1	3	1	2
A greater than 3% absolute difference exists between the hand and foot on three measures, each separated by 1 h (one point)	131	69	5	11	32	68	29	94	65	100
A less than 3% absolute difference exists between the hand and foot on three measures, each separated by 1 h	8	4	3	7	4	9	1	3	0	0
Oxygen saturation is less than 95% in the hand and foot on three measures, each separated by 1 h (one point)	89	47	7	15	15	32	13	42	54	83
Oxygen saturation is less than 98% in the hand and foot on three measures, each separated by 1 h	2	1	1	2	0	0	1	3	0	0
I do not know	12	6	10	22	2	4	0	0	0	0
Selected both correct answer options	73	39	0	0	8	17	11	35	54	83
Q17 Which of the following POx measurements meet the criteria for a PASS on the first screen (PASS means no repeat screen)										
Hand is 100% and foot is 96%	27	14	6	13	0	0	5	16	8	12
Hand is 99% and foot is 97% (one point)	157	83	21	46	42	89	30	97	64	98
Hand is 95% and foot is 91%	7	4	2	4	4	9	1	3	0	0
Hand is 94% and foot is 93%	16	8	8	17	6	13	1	3	1	2
Hand and foot must always have the same value	4	2	2	4	1	2	0	0	1	2
I do not know	4	2	3	7	1	2	0	0	0	0
Q18 On a first screen which of the following results meet the criteria for performing a REPEAT screen?										
93% in hand and 89% in foot	78	41	11	24	28	60	14	45	25	38
98% in hand and 93% in foot (one point)	127	67	9	20	29	62	24	77	65	100
94% in hand and foot (one point)	122	65	10	22	23	49	24	77	65	100
None of the above	9	5	6	13	3	6	0	0	0	0

(*Continued*)

Table 3 (*Continued*)

	Total point quartiles									
	Total		First (lowest quartile)		Second		Third		Fourth (highest quartile)	
	(*n* = 189)		(*n* = 46)		(*n* = 47)		(*n* = 31)		(*n* = 65)	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
I do not know	5	3	4	9	1	2	0	0	0	0
Selected both correct answer options	94	50	3	7	9	19	17	55	65	100
Q19 A baby receives his/her first screen and the result is 95% oxygen saturation in the hand and 89% in the foot. What happens next?										
Nurses wait an hour and rescreen	59	31	13	28	25	53	11	35	10	15
Infant is immediately referred to a physician, who personally repeats the pulse oximetry test	6	3	4	9	0	0	2	6	0	0
Infant is immediately referred to a physician, who evaluates him/her for causes of hypoxemia (one point)	96	51	6	13	20	43	16	52	54	83
Infant is sent home	0	0	0	0	0	0	0	0	0	0
I do not know	0	0	0	0	0	0	0	0	0	0
Other	9	5	4	9	2	4	2	6	1	2
Missing	19	10	19	41	0	0	0	0	0	0
Q20 What is the maximum number of times a newborn is screened if he/she never passes the screening?										
None	1	1	0	0	1	2	0	0	0	0
One	9	5	6	13	2	4	0	0	1	2
Two	29	15	5	11	16	34	4	13	4	6
Three (one point)	115	61	7	15	25	53	25	81	58	89
Four	4	2	1	2	0	0	2	6	1	2
Repeatedly until the newborn is released from the hospital	1	1	1	2	0	0	0	0	0	0
I do not know	9	5	6	13	2	4	0	0	1	2
Missing	21	11	20	43	1	2	0	0	0	0
Q22 Which numbers from the screening are you required to report to a statewide agency?										
No numbers are required for reporting	34	18	3	7	10	21	8	26	13	20
Number of screenings	54	29	13	28	12	26	11	35	18	28
Number of positives	61	32	12	26	12	26	16	52	21	32
Number of false positives	22	12	6	13	4	9	4	13	8	12
Number of refusals	50	26	11	24	9	19	11	35	19	29
Oxygen measurement for positives	21	11	7	15	3	6	1	3	10	15
I do not know	39	21	4	9	12	26	6	19	17	26
Other	33	17	6	13	9	19	6	19	12	18

Abbreviation : POx, pulse oximetry.

manage or supervise employees who screened newborns using POx, and 34 individuals who did not complete the questionnaire. Overall, nurse supervisors reported that a mean of 99% of eligible infants received POx screening.

Some questionnaire items pertained to characteristics of the respondent and the respondent's hospital of employment (note that it was possible for a nurse supervisor to represent more than one hospital or for two nurse supervisors to represent the same hospital). Approximately 60% of respondents identified as nurse managers or medical directors and 18% identified as clinical nurse specialists or RNs. Approximately 50% of the hospitals were teaching hospitals, 66% were located in nonmetropolitan areas, and 65% were privately owned.

Respondents were asked about the source of the screening protocol used by their hospital and were allowed to choose more than one selection. Approximately, 77% of respondents

indicated that their hospital used nationally endorsed protocols, 61% indicated that guidelines were from state or county policies, and 37% indicated that guidelines were from the published literature, such as New Jersey[35] and military hospital guidelines.[36] Many of these guidelines may have been in full or close agreement with nationally endorsed protocols.

Other questionnaire items pertained to the POx screening protocols followed by nurse supervisors, and we compared their answers to nationally endorsed protocols. Complete adherence to nationally endorsed protocols with a total score of 10 points was reported for 33 nurse supervisors (17% of sample). ►**Supplementary Table S2** (available in the online version) displays the point distribution. Coefficient alpha for the eight-item adherence measure was 0.76, an acceptable level (≥0.70) of reliability.[37]

Signs of suspected hypoxia were often overlooked in the three questions about screening results requiring referral to a physician to evaluate cause (questions 15, 18, and 19, with four valid answers). Only 45 (24%) of respondents selected all four options for potential hypoxia, 51% recognized that an SpO_2 below 90% and hand–foot differential greater than 3% requires immediate referral to a physician for an evaluation of the causes of hypoxia, 31% selected that the nurses would wait an hour and then rescreen in those cases instead of referring to a physician, 67% selected immediate fail for SpO_2 values under 90%, 39% selected the two repeat screenings allowed before moderately low SpO_2 becomes a fail, 67% recognized at least one, and 50% recognized both conditions (oxygen saturation and hand–foot differential) for required rescreening. In addition, 83% correctly selected the oxygen saturation of 99% in the hand and 97% in the foot (question 17) as a pass on the first screening, and almost 61% correctly cited a limit of three screening attempts (question 20) if the infant never passes the screening. Among those not receiving a point for recognizing hypoxia at SpO_2 ≤90% as an immediate fail, 56.5% were nurse managers, directors of nursing, or medical directors.

When asked about timing of the screening, 39% reported that the screening is performed around 24 hours after birth and 61% reported that screening is performed between 24 hours after birth and discharge. Both answers were given 1 point because the nationally endorsed protocol recommends screening infants at ≥ 24 hours of age or shortly before discharge if <24 hours of age. When asked about probe placement, the vast majority (92%) of respondents placed the POx probe on the right hand and either foot, which matches the nationally endorsed protocol.

Based on adjusted regression models, the association of lower policy consistency score with the following characteristics of individuals or settings was detected: (1) hospitals in early adopter states compared to hospitals in late adopter states (–1.01, 95% confidence interval [CI]: –1.76 to –0.25, $p = 0.009$); (2) hospitals with state reporting requirements compared to hospitals that are not required to report screening results (–1.23; 95%CI: –1.23 to –0.29; $p = 0.01$); and (3) nurse supervisors who were unsure about their hospital ownership status compared to those employed by private hospitals (–2.48, 95%CI: –4.77 to –1.80, $p = 0.03$). No significant differences in *policy consistency* for other hospital or individual characteristics were detected (►**Table 4**).

Patient race and ethnicity characteristics were estimated by the nurse supervisors for their hospitals. Primary race/ethnicity for each hospital was defined as the one race/ethnicity that included the highest percentage of patients. The primary race/ethnicity was non-Hispanic White for 76% of hospitals, Hispanic for 5%, and Black for 3%. For 43% of hospitals, the percentage of non-Hispanic White patients was estimated at 80% or higher. The magnitude of the Black and Hispanic populations was unknown in hospitals in which patients were primarily White.

Respondents at hospitals with primarily non-Hispanic White patients scored a mean of 7.1 points (95%CI: 6.7–7.5) and those at hospitals with primarily Black or Hispanic patients scored a mean of 7.2 points (95%CI: 6.7–7.5). We did not detect any statistical difference in points between the two groups ($p = 0.88$).

All sensitivity analyses mirrored results from the main analyses as seen in ►**Supplementary Tables S3** and **S4** (available in the online version). For the first analysis, adherence cut-off values were grouped into quartiles: first (lowest adherence-level group) 0–5 points, $n = 46$ respondents; second: 6–7 points, $n = 47$; third: 8 points, $n = 31$, and fourth: 9–10 points, $n = 65$. For the outcome of the second and third sensitivity analyses, a composite index of policy consistency using PCA was created. The eigenvalue to estimate composite index for policy consistency by PCA was 3.13. Item loadings on the principal component are provided in ►**Supplementary Table S5** (available in the online version).

Discussion

The literature has demonstrated the cost-effectiveness of POx screening, based on the assumption of perfect adherence.[38–40] However, POx screening of every eligible newborn using nationally endorsed protocols does not occur in the real world, as demonstrated by this study. Our study identified characteristics of states, hospitals, and individuals most associated with policy consistency, with scores from the questionnaire exhibiting varying rates at least 1 year after all states mandated POx screening.

Results reflected the challenges of uniformly integrating even simple evidence-based screening protocols into hospital environments under the control of different state entities.

A possible primary barrier includes training that does not effectively link pathophysiology to POx screening readings. This is represented by the responses to the questions related to hypoxia. More specifically, only 24% of respondents selected all four options for potential hypoxia, only 67% recognized ≤90% SpO_2 as an immediate failed screen, and only 51% selected that an infant with ≤90% SpO_2 in one extremity and a greater than 3% hand–foot differential would be immediately referred to a physician for evaluation of the causes of hypoxia.

Table 4 Regression results from multilevel linear regression model to evaluate the association between policy consistency and hospital characteristics

	Unadjusted				Adjusted[c]			
	Point estimate	95% CI[a]		p[b]	Point estimate	95% CI[a]		p[b]
Job title								
Nurse manager or director of nursing	Reference				Reference			
Clinical nurse specialist or RN	−0.37	−1.33	0.59	0.45	−0.21	−1.17	0.75	0.67
Other	0.37	−0.52	1.27	0.42	0.57	−0.39	1.52	0.25
Hospital teaching status								
Teaching	Reference				Reference			
Nonteaching	0.12	−0.61	0.86	0.74	−0.03	−0.81	0.75	0.94
I am not sure	0.55	−1.09	2.19	0.51	0.33	−1.38	2.04	0.70
Hospital location								
Metropolitan area	Reference				Reference			
Nonmetropolitan area	0.24	−0.54	1.01	0.55	−0.02	−1.00	0.96	0.97
I am not sure	0.38	−2.17	2.93	0.77	0.09	−2.56	2.75	0.95
Hospital ownership status								
Private	Reference				Reference			
Public	0.14	−0.63	0.91	0.72	0.19	−0.61	0.99	0.65
I am not sure	−2.04	−4.27	0.19	0.07	−2.48	−4.77	−0.20	0.03
Delivery volume in the past 12 mo								
Low volume	Reference				Reference			
Medium volume	−0.01	−0.88	0.87	0.99	−0.03	−0.91	0.85	0.95
High volume	−0.53	−1.41	0.35	0.24	−0.70	−1.80	0.40	0.21
Primary racial/ethnic group of patients								
Non-Hispanic White	Reference				Reference			
Other	−0.25	−1.09	0.59	0.57	−0.08	−0.95	0.80	0.86
State reporting requirements								
No	−0.97	−1.89	−0.04	0.04	−1.23	−2.16	−0.29	0.01
Yes	Reference				Reference			
Mandatory screening policy implementation								
Early adopters	−0.99	−1.71	−0.26	<0.01	−1.01	−1.76	−0.25	<0.01
Late adopters	Reference				Reference			

Abbreviations: CI, confidence interval; RN, registered nurse.
[a]Confidence interval.
[b]p-Value.
[c]Models were adjusted by individual job title, hospital teaching status, hospital location, hospital ownership, delivery volume in the past 12 months, primary racial/ethnic group of patients, state reporting requirements, and time of mandatory screening policy implementation with the state random effect.

There are three possible mechanisms which reduced accuracy on these questionnaire items. First, it is possible that hospital protocols did not match nationally endorsed protocols. The literature for states indicates a great variation in implementation.[41–44] Second, it is possible that hospital protocols matched nationally endorsed protocols, but nurse supervisors did not follow guidelines when performing and supervising screening. Third, it is possible that hospital protocols matched nationally endorsed protocols and nurse supervisors followed guidelines but found the questionnaire difficult because they did not have the algorithm memorized. From our unpublished qualitative study involving interviews with nurse supervisors throughout the country, many were found to rely on support materials, such as printed flowcharts or automated feedback from the electronic medical record systems when entering screening data. Thus, the first and third explanations were likely the majority of the cases.

A contributing factor to low algorithm memorization may be that respondents are not personally at the bedside performing POx screening on a regular basis. Although some

respondents may perform screening, especially in smaller hospitals or as an RN, many nurse supervisors focus entirely on administrative duties. Another potential contributor to low memorization is the complexity of the algorithm. The screening outcome (pass, fail, or repeat) is determined based on multiple decision criteria. Although reliance on support material rather than memorization of the algorithm does not imply incorrect implementation and may in fact reduce protocol errors, it is concerning that a low percentage of respondents recognized signs of hypoxia, including a $\leq$90% SpO_2 level, as an immediate failed screen that requires follow-up by a physician. Current training may not associate the pathophysiology of CCHD with SpO_2 levels and more training on the cut-off values that signal a failed screen might be needed.

One of the primary facilitators to policy consistency found in this study was a requirement to report screening results to state agencies. Although reporting screening results to administrating agencies or governments is often associated with higher policy consistency and accountability,[4,22] only some states require reporting of POx screening, at varying levels of detail.[21,22] In some cases, hospitals did not consistently report to states requiring reporting. An unexpected situation was observed in California, the only state where POx screening is offered but not mandated, and reporting to state agencies is required.[45] Compliance to reporting was poor, with one third of California's hospitals[46] not submitting screening data to the state and less than half submitting data matching the number of screens. Yet, state respondents demonstrated a higher policy consistency than those from nonreporting states, perhaps since a reporting requirement may increase accountability. It is also possible that states with the funds and infrastructure to collect screening data also have the resources for screening support, such as site visits for education, data analysis, and quality improvement feedback on POx screening practices, which could explain increased policy consistency in states with reporting requirements. Investigating those support systems should be a priority in future studies.

Our study also found that states with earlier adoption of POx screening before 2014 were associated with lower policy consistency, contradicting general expectations in implementation science of an increase in adherence for entities with a longer period of implementation due to growing awareness of new interventions by natural diffusion.[22,47] Effective training to initiate new screening protocols, as well as recurrent training updates, is critical to effective infant screening, particularly given the changes in personnel over time. The lower policy consistency among early adopters could be a sign of less robust refresher training.

Another possible explanation of lower policy consistency among earlier adopters of POx screening is that, because of the longer history of POx screening practices, some states have developed their own protocols. For example, Tennessee (TN), New Jersey (NJ), and Minnesota (MN) have their own unique algorithms for POx screening. The protocol endorsed by the Tennessee Department of Health, for instance, recommends putting the probe on either foot first. If the POx measurement is 97% or greater, the infant will pass the screening and no further screening is required. If the measurement is less than 90%, it is an immediate fail, and clinical assessment is required. If the measurement is between 90 and 96%, the POx screening procedure follows the nationally endorsed protocols. A report from TN claimed that this approach eliminated over 150,000 unnecessary POx readings without affecting the ability of POx screening to detect CCHD before discharge.[20050348] Since the cut-off value for an immediate fail is still $\leq$90% SpO_2 in TN and other states with unique protocols, the use of a different algorithm does not explain why the accuracy level on questions pertaining to immediate failed screens was so low.

This study had several limitations. First, despite extensive national recruitment efforts, the study sample size was relatively small with a cohort of 189 eligible respondents, which represented about 300,956 deliveries, or approximately, 8% of annual U.S. deliveries.[49] Therefore, generalizability of study results is unknown.

Second, despite robust dissemination of the questionnaire through national nursing and infant health organizations, representation in hospitals was disappointing for Black and Hispanic patients, with 76% of our cohort representing hospitals with White patients as the primary race. Most likely, lower funding, time constraints, or nonparticipation in agencies aiding in questionnaire dissemination may have discouraged large urban hospitals from participating. Although this study did not detect any significant statistical difference in policy compliance scores between respondents at hospitals with primarily non-Hispanic White patients and those at hospitals with primarily Black or Hispanic patients ($p = 0.88$), including nursing organizations specifically representing more diverse nursing populations is essential for future stages.

Third, our response rate is unknown, since snowball techniques often mask the number of individuals receiving the study invitation.

Fourth, to reduce response burden, policy consistency was evaluated based on only eight questions. More specific questions, including items differentiating POx screening protocols in well-baby nurseries from protocols in newborn intensive care units (NICUs), may have provided more insight. No national recommendations have been made for screening in higher level nurseries beyond level 1, so this study focused on general procedures in POx screening of infants as part of the standard RUSP panel and was not intended to reflect NICUs or higher-level nurseries, where escalation of health care response incorporates internal procedures for monitoring for heart defects. In addition, the questionnaire asked about fail conditions that required referral to a physician for further evaluation but did not ask about the actual referral protocols. Our as yet unpublished qualitative study suggested that physician referral and follow-up procedures for cases of suspected hypoxia vary widely across different hospitals and physicians.

Fifth, respondents were nurse supervisors who may not regularly perform bedside caregiving duties such as POx screening, thereby increasing the likelihood that respondents did not have the algorithm memorized. Many hospitals

provide printed flowcharts and automatic feedback built into the electronic medical record systems, which help screeners correctly categorize POx readings without needing to memorize the algorithm. For nurse supervisors who did not have the algorithm committed to memory and did not utilize support materials during questionnaire completion, answers may not have mirrored actual practices.[21,50]

Sixth, the same hospital could have been represented by more than one respondent, and the same respondent could have represented more than one hospital.

Last, whether causality played a role in lower policy consistency evidenced in this study is impossible to know, since this is an observational study based on nurse supervisor self-reports. For example, it is unlikely that supervisors not knowing the ownership status of the hospital was a direct cause of lower policy consistency. It is more likely that lack of knowledge about ownership status was due to being a contract or new employee, which may have also affected policy consistency. Thus, it was important to follow-up with the qualitative study to interview questionnaire participants with respect to the entire screening process, implementation, and screening barriers and facilitators.

Conclusion

Our study revealed that a low percentage of respondents selected all four options for potential hypoxia. It is noteworthy that almost one-third of respondents did not recognize SpO_2 $\leq$90% as a failed screen that requires immediate physician follow-up. One possible explanation is that the nurse managers rely on support materials or feedback built into electronic medical record systems when entering screening data. Therefore, they do not memorize the screening algorithm. Enhanced training to associate POx screening readings with knowledge of pathophysiology of hypoxia may increase the recognition of hypoxia, especially hypoxia at $\leq$90% SpO_2 that requires immediate physician follow-up. Another novel finding of this study is that hospitals with no requirement to report results to state agencies, as well as hospitals in early adopter states, were associated with lower policy consistency. Implementing state reporting requirements and refresher training might increase the policy consistency. On the other hand, use of a modified protocol unique to a particular state, which deviated from the nationally endorsed protocol, might have decreased policy consistency scores in the early adopter states. Further observation is needed to clarify the cause of the lower policy consistency among early adopter states compared to later adopter states.

Note

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Conflict of Interest

None declared.

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