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Pulse oximetry screening for congenital heart defects in newborn infants: an evaluation of acceptability to mothers

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ABSTRACT

Background Introducing neonatal screening procedures may not be readily accepted by parents and may increase anxiety. The acceptability of pulse oximetry screening to parents has not been previously reported.

Objective To assess maternal acceptability of pulse oximetry screening for congenital heart defects and to identify factors predictive of participation in screening.

Design and setting A questionnaire was completed by a cross-sectional sample of mothers whose babies were recruited into the PulseOx Study which investigated the test accuracy of pulse oximetry screening.

Participants A total of 119 mothers of babies with false-positive (FP) results, 15 with true-positive and 679 with true-negative results following screening.

Main outcome measures Questionnaires included measures of satisfaction with screening, anxiety, depression and perceptions of test results.

Results Participants were predominantly satisfied with screening. The anxiety of mothers given FP results was not significantly higher than that of mothers given true-negative results (median score 32.7 vs 30.0, p=0.09). White British/Irish mothers were more likely to participate in screening, with a decline rate of 5%; other ethnic groups were more likely to decline with the largest increase in declining being for Black African mothers (21%, OR 4.6, 95% CI 3.8 to 5.5). White British mothers were also less anxious (p<0.001) and more satisfied (p<0.001) than those of other ethnicities

Conclusions Pulse oximetry screening was acceptable to mothers and FP results were not found to increase anxiety. Factors leading to differences in participation and satisfation across ethnic groups need to be identified so that staff can support parents appropriately.

What is already known on this topic?

- Pulse oximetry can be used as a potential screen for congenital heart defects.
- Pulse oximetry screening is more sensitive than currently available procedures and adds value to current screening.

What this study adds

- Pulse oximetry screening is acceptable to parents and false-positive results do not cause lasting anxiety.
- Parents may find information on heart defects and their treatment helpful.
- Differences in participation and satisfaction across ethnic groups need further investigation.

INTRODUCTION

Congenital heart defects (CHDs) are the commonest group of congenital malformations.[1–3] CHD causes up to 40% of deaths from congenital abnormalities[1 4] and 3%–7.5% of infant deaths.[5 6] If life-threatening critical defects are not detected early, they can be associated with poor outcomes. Pulse oximetry is a potential screening tool for CHD in newborns which has not yet been widely adopted.[7] The PulseOx Study evaluated the test accuracy of pulse oximetry in this respect. The study reported that pulse oximetry screening is likely to identify cases of critical CHD which would otherwise go undetected.[8] The present paper reports the acceptability of pulse oximetry screening to mothers whose babies were screened during the PulseOx Study.

When new antenatal or neonatal screening programmes are introduced, it is important to consider the acceptability of screening to parents, and the psychological impact of the screening procedure. Screening may raise anxiety as it introduces the possibility that a child may have a serious health condition. Screening acceptability has an effect on uptake and the effects of inaccurate results may extend over a considerable time.[9–12] These issues have not been addressed for pulse oximetry screening.[7] It is therefore important to examine parents' experience of testing, whether anxiety is increased, and whether any heightened anxiety persists.[10]

Evidence of relationships between demographic factors and screening acceptability is limited.[13] Willingness to participate and acceptability of perinatal screening for Group B Streptococcus varied with age and ethnicity.[14] The same study found satisfaction varies with maternal anxiety and perceptions of the illness. Understanding factors underlying satisfaction and negative emotions allows vulnerable groups to receive support when making decisions about participating in screening.

Aims

The aims of the study were (1) to identify factors predicting participation in pulse oximetry screening, maternal satisfaction and anxiety and (2) to assess satisfaction with screening and distress across three groups (those with true-positive (TP), false-positive (FP) and true-negative (TN) results).

METHODS

Participants and procedures

The PulseOx Study recruited newborns from six maternity units between February 2008 and January 2009.[8] Mothers who participated were invited to complete a cross-sectional questionnaire. For babies identified as FP, questionnaires were given to mothers before discharge from hospital or posted to their home; a follow-up questionnaire was sent 1 year later to those who returned a baseline questionnaire. Mothers of babies with TP results were approached when healthcare staff perceived them to be ready to respond. Questionnaires were administered face-to-face or given to mothers to complete before discharge. A sample of mothers whose babies received TN results over a 2-month period were approached to complete questionnaires at the time of discharge from hospital.

Demographic and clinical information

Demographic information (age, ethnicity, parity) was collected from all women approached to take part in the PulseOx Study. Data on testing, including pulse oximetry status (TN, FP, TP) were obtained from the PulseOx Study database.[15]

Main questionnaire

To measure maternal satisfaction, subscales were developed to assess satisfaction with information; opportunities to discuss the test; opportunities to change minds about having the test; happiness with test; confidence in test; and post-test communication satisfaction. Subscales' mean scores were summed to create the Overall Satisfaction scale; higher scores indicated higher satisfaction. A further item (stress) assessed the mother's perceived stress during testing; higher scores indicated higher stress.

Anxiety was assessed using the short form of the Spielberger state-trait anxiety inventory.[16 17] Higher scores indicate higher anxiety. Depression was measured using the depression subscale of the Hospital Anxiety and Depression Scale.[18] Higher scores indicate higher depression.

General feelings about the test were addressed: mothers were asked to indicate whether they thought the test was important for their baby, for all babies and whether heart problems would have been found without the test. Higher scores indicated more positive perceptions of the test.

Participants were asked what they thought the pulse oximetry test showed (no problem, minor heart/non-heart condition, serious heart/non-heart condition, 'don't know', 'other'). A binary scale was created: 0=no problem or 'don't know'; 1=all other responses.

Items assessing illness perceptions (consequences of CHD; timeline of illness; whether the condition could be effectively treated or controlled (treatment control); extent to which the illness makes sense (illness comprehensibility)) were adapted for the context of heart disease in babies from the Brief Illness Perception Questionnaire.[19] Higher scores indicate perceptions of higher severity, longer timeline, less treatment control and lower illness comprehensibility.

A two-item version of the Life Orientation Test was used to measure dispositional optimism.[20 21] With the present data, the correlation between these item scores was low (r_s=0.19, p<0.001) so the items were analysed separately.

Finally, participants were invited to add free comments and ideas for improving the test procedure.

Follow-up questionnaire (FP group only)

Items assessing *satisfaction with information, anxiety* and *general feelings about the pulse oximetry test* were presented as in the Main Questionnaire. Open comments were invited.

Analysis

The likelihood of declining entry into the study with respect to age, parity and ethnicity was examined using a multivariate logistic regression model. Covariates were first considered individually and then in combination if statistically important (p<0.1).

Differences in anxiety, depression, general feelings about the test and satisfaction measures between TN and FP groups were examined using Mann–Whitney U. Differences in anxiety, depression and overall satisfaction were also examined by maternal perceptions of the test results using Mann–Whitney U. Wilcoxon matched pairs test was used to detect change in anxiety over time for participants in the FP group. Variable distributions were inspected and log transformed where appropriate; directions of effect were maintained. One-way analyses of variance (ANOVA) were computed to identify differences in anxiety, depression and overall satisfaction by ethnicity. Hierarchical multiple regression equations were calculated to identify characteristics that would predict anxiety and overall satisfaction. Free-text comments were thematically analysed using a Framework approach.[22]

Research ethical approval was obtained (Trent REC ref:07/MRE04/40).

RESULTS

Participation in screening

Mothers of 20 055 babies participated in the PulseOx Study, 2005 declined. Parity (p<0.0001) and ethnicity (p<0.0001) had an effect on the likelihood of declining; mother's age did not (p=0.2) (table 1). Compared with the largest ethnic group (White British and Irish), which had the lowest rate of declining (5%), all other major ethnic groups had an increased likelihood of declining (table 2); the largest increase was for Black African mothers (21%, OR 4.6, 95% CI 3.8 to 5.5, p<0.0001). Mothers with more than one baby were more likely to decline than first-time mothers, this was particularly evident in mothers with four or more children (14% vs 7%, OR 1.5, 95% CI 1.3 to 1.7, p<0.0001).

Participation in questionnaire study

Of 169 mothers of babies with FP results, 148 were approached to complete a questionnaire and 119 (80.4%) responded. The median time to questionnaire completion after the birth was 30 days (IQR 12–58). Follow-up questionnaires were obtained from 51 FP participants (42.9%) and were completed at a median of 385 days after birth (IQR 355–417). Of 26 mothers of babies with TP results, 21 were approached to complete a questionnaire; 15 (71.4%) participated. The median time from birth to questionnaire completion was 20 days (IQR 3–29). Six hundred and seventy nine mothers of babies with TN results returned questionnaires over a 2-month period.

Table 1 Proportions of women in the age, ethnicity and parity groups who declined to participate in screening. 'Missing' data were missing from the records of participants who declined

	Proportion in sample, n=22060 n (%)	Number who declined	Percentage of group who declined
Age group			
<20	1586 (7.2%)	112	7.1%
20–24	5027 (22.8%)	486	9.7%
25–29	6448 (29.2%)	615	9.5%
30–34	5240 (23.8%)	456	8.7%
35–39	2988 (13.5%)	222	7.4%
≥40	727 (3.3%)	70	9.6%
Missing	44 (0.2%)		
Ethnicity			
White (British and Irish)	11223 (50.9%)	605	5.4%
Asian (Indian)	1374 (6.2%)	152	11.1%
Asian (Pakistani)	3361 (15.2%)	553	16.5%
Asian (Bangladeshi)	569 (2.6%)	108	19.0%
Black (Caribbean)	625 (2.8%)	76	12.2%
Black (African)	854 (3.9%)	182	21.3%
Other	2960 (13.4%)		
Missing	1094 (5.0%)		
Parity			
1	9906 (44.9%)	709	7.2%
2	6387 (29.0%)	587	9.2%
3	3168 (14.4%)	334	10.5%
4+	2588 (11.7%)	364	14.1%
Missing	11 (<0.1%)		

Table 2 ORs of declining by ethnicity.

Comparison with White (British and Irish)	OR (95% CI)
Asian (Indian)	2.2 (1.8 to 2.7)
Asian (Pakistani)	3.3 (2.9 to 3.7)
Asian (Bangladeshi)	3.9 (3.1 to 4.9)
Black (Caribbean)	2.4 (1.9 to 3.1)
Black (African)	4.6 (3.8 to 5.5)

The median number of days from the baby's birth to questionnaire completion was one (IQR 0–2).

Test results and participant perceptions of results

The majority of participants with TN results thought the test showed no problem with their babies' health (table 3). For those with FP results, just under half believed the test showed no problem. Most TP participants believed the test showed a serious problem.

Emotional state and satisfaction by test result

Table 4 summarises the scores for anxiety, depression and overall satisfaction, satisfaction subscales and participants' general feelings about the test. The mean anxiety scores for mothers of babies with TN and FP results were 31.37 (95% CI 30.50 to 32.24; median=30) and 33.30 (95% CI 31.01 to 35.59; median=32.7), respectively. These scores are within the lower part of the normal range for women in this age group.[17]

Mothers of babies with TP results had high anxiety and depression scores compared with the other two groups, but similar scores on satisfaction measures. This was not tested statistically because of this group's small size. Significant differences between the two larger groups (TNs and FPs) were seen on depression and satisfaction measures; FP participants were more depressed ($Z=-2.66$; $p=0.01$) and less satisfied ($Z=-8.91$ to -3.56, $p<0.001$). Anxiety was not significantly elevated in the FP group ($Z=-1.71$, $p=0.09$) and although statistically significant, the difference in median depression between FP and TN participants was only 1 point which is unlikely to be clinically significant. Differences were not seen in the perceived importance of the test. Median scores indicate that most people were satisfied with test procedures.

Table 3 Frequencies of parent perceptions of test results for each group

Parent perception of test results	True-negative frequency (%)	False-positive frequency (%)	True-positive frequency (%)
No problem	599 (88.2)	56 (47.1)	1 (6.7)
Minor heart condition	5 (0.7)	29 (24.4)	1 (6.7)
Minor health condition, not heart condition	2 (0.3)	11 (9.2)	0 (0)
Serious heart condition	8 (1.2)	2 (1.7)	11 (73.3)
Serious health condition, not heart condition	0 (0)	2 (1.7)	0 (0)
Don't know	16 (2.4)	7 (5.9)	1 (6.7)
Other	34 (5.0)	11 (9.2)	0 (0)
Missing data	15 (2.2)	1 (0.8)	1 (6.7)

For the FP group, there was no significant change over time in Anxiety ($Z=-0.24$, $p=0.81$), post-test communication satisfaction ($Z=-0.93$, $p=0.36$), the importance of their baby and all babies being tested ($Z=-1.51$, $p=0.13$; $Z=-1.58$, $p=0.12$ respectively), or whether they believed a heart problem would be found without the test ($Z=-0.34$, $p=0.73$).

One-way ANOVA showed differences by ethnicity on anxiety, depression, overall satisfaction and stress ($F(5, 574)=8.89$, $p<0.001$; $F(5, 624)=5.63$, $p<0.001$; $F(5, 611)=5.35$, $p<0.001$; $F(5, 640)=6.88$, $p<0.001$, respectively). Post-hoc analyses indicated that participants of Indian, Pakistani and Bangladeshi origin were more anxious than White (British and Irish) mothers; Indian and Pakistani mothers were more depressed than White (British and Irish) mothers; Indian participants were less satisfied than White (British and Irish) participants and Pakistani participants reported more stress than White (British and Irish) participants.

Factors associated with anxiety and satisfaction

A bivariate measure of ethnicity (White (British and Irish)/all others) was used in multiple regression analyses. More optimistic and less depressed participants were less anxious ($\beta=-0.16$, $p<0.001$; $\beta=-0.11$, $p=0.01$; $\beta=0.27$, $p<0.001$); White (British and Irish) participants were less anxious than other participants ($\beta=0.13$, $p=0.001$). Higher overall satisfaction predicted lower Anxiety ($\beta=-0.14$, $p=0.001$) (appendix A).

FP participants reported lower overall satisfaction than TN participants ($\beta=-0.21$, $p<0.01$) (appendix B). Perceiving treatment to be more helpful and perceiving a higher understanding of heart disease in babies predicted higher overall satisfaction ($\beta=-0.11$, $p=0.01$; $\beta=-0.10$, $p=0.01$). White (British and Irish) participants were more satisfied overall than were people of other ethnicities ($\beta=-0.10$, $p=0.02$). Mothers who reported finding the testing process more stressful were less satisfied overall ($\beta=-0.17$, $p<0.001$).

Table 4 Median scores (IQR) for each test result group on anxiety, depression, 'general feelings about the test', satisfaction and stress measures and significance of differences between true-negative and false-positive (time 1) scores (Mann–Whitney U)

	True-positive		True-negative		False-positive time 1		False-positive time 2		Difference between TN and false-positive (time 1)
	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	Median (IQR)	n	p Value
Anxiety; possible range: 20–80	48.3 (25–67.7)	14	30 (20–36.7)	594	32.7 (23.3–40)	102	30 (20–36.7)	47	0.09
Depression; possible range: 0–21	7.5 (5.6–12)	14	3 (2–6)	644	4 (2–7)	115			0.01
Important for your baby to have test?	5 (5–5)	14	5 (5–5)	678	5 (5–5)	118	5 (5–5)	51	0.95
Important for all babies to have test? 1='Definitely not'; 5='Yes definitely'	5 (5–5)	14	5 (5–5)	676	5 (5–5)	117	5 (5–5)	51	0.63
Would have found heart problem without test? 1='Yes, definitely; 5='Definitely not'	3 (2–4)	14	3 (2–3)	674	3 (3–4)	116	3 (2–4)	50	0.003
Overall satisfaction (possible scale range: 1–30)	20.5 (18.3–22.8)	12	23 (21–25)	637	20 (18.5–23.1)	109			<0.001
Satisfaction with information	4 (4–4.8)	12	4.67 (4–5)	661	4 (4–5)	108	4 (3.7–5)	50	<0.001
Opportunities to discuss (item 4)	4 (3.5–4)	13	5 (4–5)	667	4 (4–5)	116			<0.001
Opportunities to change mind (item 5)	4 (3.5–4)	13	5 (4–5)	659	4 (4–5)	111			<0.001
Happiness with test	4.5 (4–5)	13	5 (4–5)	674	4 (4–5)	115			<0.001
Confidence in test	4 (4.5)	13	5 (4–5)	668	4 (3.5–5)	115			<0.001
Post-test communication satisfaction (possible subscale ranges: 1–5)	4 (3.9–5)	14	4.67 (4–5)	661	4 (3.33–5)	117			<0.001
Stress (possible scale range: 1–5)	2 (2–4)	13	1 (1–2)	667	3 (2–4)	114			<0.001

Parental comments

Free response comments were given by 124 participants on 139 questionnaires (7 TP; 67 TN; 41 FP for the first questionnaire; 24 FP for the second questionnaire). Perceptions of screening were predominantly positive: quick, safe, non-invasive, painless, non-distressing for the baby and reassuring for parents. Of high importance was its potential to detect problems early, before discharge, allowing treatment to start and lives to be saved. Many parents were glad to have had the opportunity to screen. Some reported gratitude, particularly when screening identified a health condition. Participants from all groups felt that screening should be standard care; many would recommend the test to others.

At the time of testing, some participants thought it would be useful to have more information on how the test is conducted, what it does and what happens after testing. One reported that standard statements in the research information sheet (relating to study risks) contributed to anxiety about participating – 'says we do not take any responsibility for any damages really scares us and you are in two minds' (TN respondent).

An area of concern was what happened when babies 'failed' a test – 'We did get the impression that the midwives and baby doctor did not fully understand the protocol when the test failed . . . this led to increased anxiety' (FP respondent). Communication of test results was important: some felt staff could have been more reassuring, or would have liked more information about what the result meant. Where communication problems were perceived, worry and anxiety were exacerbated.

DISCUSSION

This is the first study to assess the acceptability to mothers of pulse oximetry as a neonatal screening procedure. Mothers were predominantly satisfied with pulse oximetry screening, perceiving it as an important and valued test to detect ill babies. Our findings would suggest that the routine implementation of pulse oximetry screening would be generally acceptable. It is worth noting that babies who screened positive were treated in accordance with the protocol for this specific study[15]; acceptability may differ where alternative protocol are followed. However, we do not believe that alternative published screening protocols differ significantly from PulseOx in any way which may cause additional concern to parents.

Mothers given FP results were not found to be more anxious after taking part in the screening processes than those given TN results, though they were less satisfied with the test and gave higher depression scores (a small but statistically significant difference). Participants given FP results recalled the testing process as more stressful, probably reflecting uncertainty and the need for further testing. Now the accuracy of the test is more clearly defined,[8] staff can be more informative about what the result means for an individual.

Higher anxiety was predicted by lower optimism, lower overall satisfaction, higher depression and ethnicity. White (British/Irish) participants were more satisfied with screening than those of other ethnicities and thought needs to be given to culturally appropriate support and information for parents. Satisfaction was predicted by lower stress, anxiety and depression, but also by a higher evaluation of treatment's ability to

control heart disease and the comprehensibility of heart disease. This suggests that people who felt they understood heart disease and who believed something could be done about the illness were perhaps more willing to put up with the testing procedure. It may be helpful to focus information on increasing understanding of heart disease and its treatments.

White British and Irish mothers were more likely to participate in the PulseOx Study than other ethnic groups. A similar pattern was found in a study of perinatal screening for Group B Streptococcus.[14] Since the completion of the PulseOx Study, three study centres have continued with the screening protocol as part of standard care. Uptake has been almost universal, suggesting that the research context was off-putting, rather than the actual screening process. Observations by staff who took consent and carried out screening during the PulseOx Study support this. At one hospital, staff perceived South Asian mothers to be less likely to participate, either because of difficulties in comprehending study information (even though material was presented in a range of languages) or because mothers were more likely to want to wait for their partners before deciding whether to give consent.[15] The factors leading to non-participation and differences in satisfaction across groups need to be further explored before further conclusions can be drawn about how participation and satisfaction can be increased.

Limitations

There was no follow-up TN group for comparison with the FPs because of constraints imposed by the Research Ethics Committee. However, as there was no significant difference in anxiety at baseline between TN and FP participants, and anxiety did not change over time for FP participants, this omission is less problematic than if anxiety had been elevated for mothers receiving FP results.

An untested variable that may have affected emotional state or satisfaction with screening was the time between birth and questionnaire completion. An individual completing a questionnaire on discharge might be more anxious and the test would be more salient than for someone completing the questionnaire later. Unfortunately, this variable was heavily confounded by test result group, with TN participants receiving the questionnaire on discharge while FP participants often received it by post. Nevertheless, our results suggest that, even if anxiety does increase immediately after testing, it is not a lasting effect and soon returns to a level comparable with the TN group.

It is unfortunate that, due to ethical constraints, only demographic data could be collected for individuals who declined to participate. As pulse oximetry screening at three local hospitals is being taken up by almost all mothers outside the research context, it would appear that it is the research process that is deterring mothers rather than the actual screening itself. However, it is still important to better understand why some people decline to take part in research so that the issues can be addressed and ensuring that research findings are representative and generalisable.

CONCLUSIONS

Pulse oximetry screening was widely acceptable to parents; FP results did not cause lasting anxiety. Careful communication of results needs to be conducted to minimise parental anxiety while avoiding false reassurance. Parents may need information on heart defects in order to understand better both the screened conditions and the importance of testing. Factors leading to differences in participation and satisfaction across ethnic groups need to be identified so that staff can support parents appropriately.

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