Quality Improvement in Screening for Critical Congenital Heart Disease

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Objectives Screening for critical congenital heart disease with pulse oximetry requires healthcare providers to decipher a previously published algorithm, a feature that raises concerns about quality of interpretation of pulse oximetry results. We hypothesized that this method would be prone to error and a computer-based tool would lead to a more accurate interpretation of the screening results.

Study design In this randomized crossover study, healthcare providers with prior experience using pulse oximetry received 2 sets of 10 mock screening scenarios and were asked to interpret the results of each scenario as "pass," "fail," or "retest." Participants were randomized to use either the paper algorithm or computer-based tool for the first set of 10 scenarios and the alternative method for the second set. We used Wilcoxon rank sum tests to compare the accuracy of interpretation using the 2 methods.

Results The 102 participants answered 81.6% of the scenarios correctly when manually interpreting the algorithm vs 98.3% correct when using the computer-based tool ($P < .001$). These differences were most pronounced for the "fail" scenarios (65.4% manual vs 96.7% computer, $P < .001$) and the "retest" scenarios (80.7% manual vs 98.7% computer, $P < .001$), but were also significant for the "pass" scenarios (94.1% manual vs 99.0% computer, $P < .001$).

Conclusions Use of a manual algorithm for the interpretation of results in screening for critical congenital heart disease with pulse oximetry is susceptible to human error. Implementation of a computer-based tool to aid in the interpretation of the results may lead to improved accuracy and quality. *(J Pediatr 2014;164:67-71)*.

In 2011, critical congenital heart disease (CCHD) was added to the US Recommended Uniform Screening Panel. Infant mortality for children with CCHD has slowly been improving over the last 30 years, with infant survival increasing from 67.4% for those born 1979-1993 to 82.5% for those born 1994-2005.[1] Earlier detection of CCHD offers the promise of even further reduced morbidity and mortality for children with CCHD.[2] Unfortunately, 31.3% of children with CCHD are not diagnosed until after the first day of life.[1] Pulse oximetry is a simple, noninvasive, bedside test that can accurately detect the percent of hemoglobin saturated with oxygen; infants with CCHD typically have a low percent saturation even before the onset of symptoms.[3] Of course, not all children with CCHD will be detected via pulse oximetry; screening with pulse oximetry should, thus, be considered an adjunct to the status quo of clinical assessments, not a replacement. Nevertheless, through earlier detection, screening with pulse oximetry holds the promise of improving morbidity and mortality for newborns with CCHD.[1,4] Indeed, newborn screening for many other disorders has proven to significantly improve outcomes for children with those disorders.[5-7]

However, there is a notable difference between screening for CCHD and screening for other disorders in newborns: the need for bedside interpretation of data by the healthcare provider.[8] In the 29 core conditions on the Recommended Uniform Screening Panel that utilize bloodspots, a laboratory blood test is used to detect the presence of the condition.[9] In early detection of hearing loss, bedside devices use automated algorithms to deliver a "pass" or "fail" result; no human interpretation of data is needed.[10]

For CCHD screening, current guidelines recommend that a healthcare professional use a flowchart to interpret the findings from pulse oximetry performed on the right hand and either foot at >24 hours of age (**Figure 1**); these guidelines have been endorsed by the American Academy of Pediatrics, the American College of Cardiology, and the American Heart Association.[11,12] With this algorithm, pulse oximetry is recommended to be performed in asymptomatic term neonates ≥24 hours of age in both the right hand (to obtain a saturation that is typically preductal) and either foot (to obtain a saturation that is postductal). If the saturation in either location is <90%, then the child has a positive screen (fails screening) and further workup such as an echocardiogram is recommended. If the saturation is ≥95% in either location, and the difference between the 2 saturations is ≤3%, then the child has a negative screen (passes screening), and no further screening or workup for CCHD is recommended. If neither of these conditions is met, repeat screening is recommended in 1 hour. If the conditions are still not met upon repeat screening, a third screening is recommended in an hour. If the child does not meet criteria for a negative screen at this third screening, then the child is considered to have a positive screen. To ensure success of any screening program for CCHD with pulse oximetry, appropriate interpretation of this algorithm is necessary.

CCHD Critical congenital heart disease

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The authors declare no conflicts of interest.

Portions of this study were presented as an abstract at the American College of Cardiology Scientific Sessions, March 9-11, 2013, San Francisco, CA.

0022-3476/$ - see front matter. Copyright © 2014 Mosby Inc. All rights reserved. http://dx.doi.org/10.1016/j.jpeds.2013.08.044

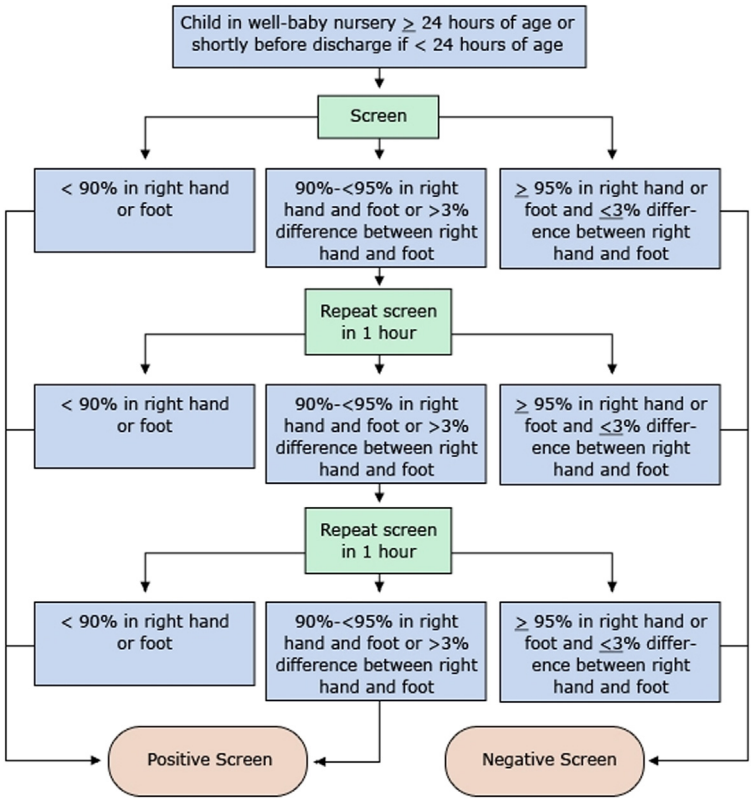

Figure 1. Algorithm for screening for CCHD. Screening protocol endorsed by the American College of Cardiology, the American Academy of Pediatrics, and the American Heart Association (Reprinted from the public domain from the U.S. Centers for Disease Control and Prevention. Available at http://www.cdc.gov/ncbddd/pediatricgenetics/pulse.html).

For hospitals that planned on using human interpretation of an intricate flowchart, we were concerned about whether healthcare professionals would indeed interpret the findings appropriately. The purpose of this study was to assess the accuracy of interpretation of screening results using the paper algorithm vs a computer-based tool. We hypothesized that human interpretation of a paper flowchart would be prone to error and a computer-based tool would lead to more accurate interpretation of the screening results.

Methods

We performed a randomized crossover study at Children's Healthcare of Atlanta in 2012 to compare the performance of a paper algorithm vs a computer-based tool for interpretation of results from screening newborns for CCHD with pulse oximetry. An online computer-based tool was developed in-house for the purposes of this quality initiative. Healthcare providers familiar with how to use pulse oximetry in newborns were eligible for the study. Screening of newborns with pulse oximetry was not part of the standard of care in our facility at the time of this study, but the use of pulse oximetry in symptomatic infants was routine. Each of the participants was given 2 sets of 10 hypothetical screening scenarios and was asked to interpret the results of each scenario as "pass" (negative screen), "fail" (positive screen), or "retest" (repeat screen recommended) by marking the appropriate option for each scenario on the test (**Appendix 1**; available at www.jpeds.com). Unknown to the participants, each set contained 4 "pass" scenarios, 3 "fail" scenarios, and 3 "retest" scenarios. Participants were randomized to use either the paper flowchart or the computer-based tool for the first set of 10 scenarios; each participant then used the alternative method for the second set. When using the paper flowchart, participants received a copy of the flowchart to consult while considering each scenario. When using the computer-based tool (**Appendix 2**; available at www.jpeds.com), participants were asked to input the relevant data into the online tool and then to press a button to submit the data. The computer program then used the algorithm to interpret the submitted data and display the recommended interpretation. After completing the 20 scenarios, participants were asked to give their opinions about the ease of use of the 2 options using a Likert scale (1 = very easy, 2 = easy, 3 = difficult, 4 = very difficult), their likelihood to use a computer option if offered, and their preference for which option to use in practice. Because this was a quality improvement project without the collection of any protected health information, this study was not reviewed by the institutional review board.

We used χ^2 analysis to compare the composition of the 2 groups and Wilcoxon rank sum tests to compare the accuracy of interpretation using the 2 methods, accounting for the crossover design. We compared results in total and performed subanalyses for the 3 types of scenarios: "pass," "fail," and "retest." We used an unpaired t test to compare the perceived ease of use of the 2 options. All analyses were performed using SAS 9.3 (SAS Institute, Cary, North Carolina), and statistical significance was considered at the $P < .05$ level.

Results

There were 102 participants in the study, 75 of the participants were nurses, and the other 27 were respiratory therapists (16), physicians (5), medical or nursing students (4), physician assistant (1), and not collected (1). There was no difference in the percentage of nurses in the 2 groups: 70.6% of the group using the paper flowchart first vs 76.5% of those using the computer-based tool first ($P = .50$).

Overall, the participants answered 81.6% of the scenarios correctly when using the paper flowchart vs 98.3% correct when using the computer-based tool ($P < .001$). These differences were most pronounced for the "fail" scenarios (65.4% for the manual algorithm vs 96.7% for the computer-based tool, $P < .001$) and the "retest" scenarios (80.7% for the manual algorithm vs 98.7% for the computer-based tool, $P < .001$), but were also significant for the "pass" scenarios (94.1% for the manual algorithm vs 99.0% for the computer-based tool, $P < .001$) (Figure 2).

Participants found the computer-based tool significantly easier to use than the paper algorithm (Figure 3). Over 90% of participants found the computer-based tool very easy to use, and none found it to be difficult or very difficult. In contrast, no participants believed that the paper algorithm was very easy to use, and 67% of them said that it was difficult or very difficult. These findings corresponded to a mean Likert score of 2.81 for the paper algorithm vs 1.08 for the computer-based tool ($P < .001$). Furthermore, when asked how likely one would be to use a computer-based tool if offered, 97% were likely or very likely to use the tool. Given the option of using the paper algorithm or computer-based tool in practice, 95% preferred the computer.

Discussion

In a screening program that has been shown to have a high false negative rate of 38% in a controlled research setting,[13] our findings raise concern that using solely the paper algorithm for screening newborns for CCHD may result in an even higher effective false negative rate in practice because of human error. In our mock scenarios in which the correct answer should have been "fail," participants using the paper algorithm chose the correct option only 65% of the time. In an ideal setting, screening should aim to identify all of those patients who have disease; that is, the ideal screening program should have high sensitivity and, thus, a corresponding low false negative rate.[14] Our findings suggest that relying on human interpretation of the paper algorithm may limit the success of screening for CCHD by raising the false negative proportion. The success of screening for CCHD is already limited by the fact that many children with CCHD (eg, coarctation of the aorta) may not have hypoxemia and would, thus, not be detected through pulse oximetry, underscoring the need for detailed clinical assessments to evaluate for CCHD during the newborn period.

Although our study was not designed to determine why or how participants failed with either the paper or computer algorithms, our personal observations as participants completed the surveys and comments from those participants do shed some light on potential factors leading to errors. For the paper algorithm, participants appeared to have difficulty following the algorithm when there was a >3% difference between the upper and lower extremity measurements or when it was the third test for that subject. Modifications of the algorithm, as have been implemented in New Jersey[15,16] and Tennessee,[17] may help decrease these errors. For the computer-based tool, the few incorrect responses appeared to be due to incorrect data entry on the part of the participant (eg, not changing the test option to third test). This error can be corrected by not allowing participants to "go back" on the computer tool and, thus, requiring participants to enter the test number each time.

Our findings are consistent with prior efforts in pediatrics to reduce human error by means of the aid of a computer. First, computer tools can be useful in reducing errors in diagnosis. In a study evaluating cardiologist interpretation of pediatric electrocardiograms, the use of a computer tool reduced misreading or misinterpretation of electrocardiograms by 83%.[18] Second, computer tools can help to prevent

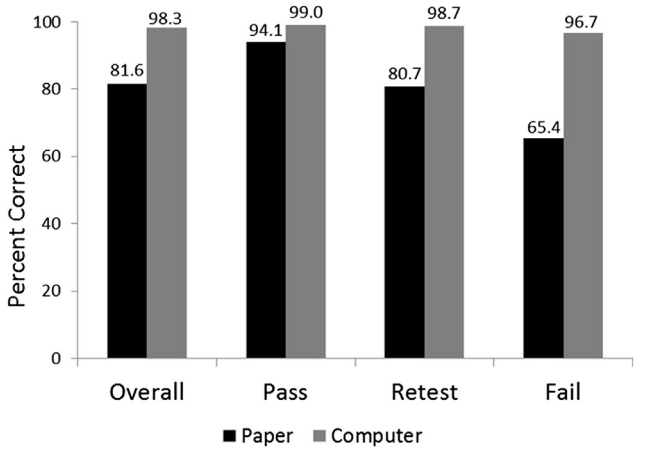

Figure 2. Accuracy when using a paper algorithm vs a computer-based tool. In 20 mock scenarios for screening for CCHD using pulse oximetry, those using the computer-based tool identified the correct answer more often than those using the paper algorithm ($P < .001$ for paper vs computer in all comparisons).

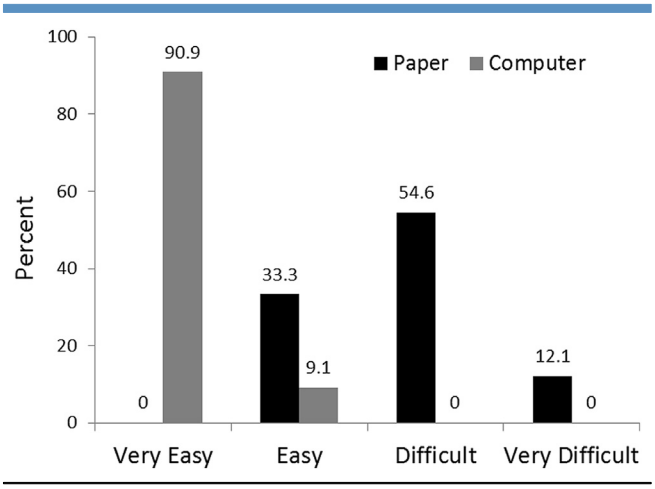

Figure 3. Participants' perceived ease of use of paper algorithm vs a computer-based tool. In screening for CCHD using pulse oximetry, participants found the computer-based tool to be easier to use than the paper algorithm ($P < .001$).

errors in treatment. In a pediatric intensive care unit setting, computer physician order entry combined with computer decision combined with a clinical decision support system reduced prescription errors by 83% and potential adverse drug events by 72%.[19] Similarly, in a neonatal intensive care unit, when an online ordering system for total parental nutrition replaced the traditional paper system, errors in the orders were reduced by 89%.[20] Indeed, the use of computer-based tools to aid in the evaluation and management of children is an area ripe for further research and development.[21] Integration of computer-based tools with electronic medical records would allow for seamless data collection and follow-up to track the outcomes and management as a result of screening.

This study is not without its limitations. First, these results were determined from mock scenarios and not actual practice. In these scenarios, "pass" was the correct answer in 40% of cases, but "pass" is expected be the correct answer in the vast majority of cases in real practice. With the "pass" scenarios being the least likely to be misinterpreted in our study, the percent of "overall" correct answers in actual practice would be expected to be higher than in our study. Second, although participants were familiar with the use of pulse oximetry in newborns, pulse oximetry was not used for routine screening in our hospital at the time of the study. Because this may have been some participants' first exposure to interpreting the algorithm, our findings would not reflect the impact of any potential learning curve in using the algorithm. That is, with more experience in using the algorithm, it is likely that fewer errors would be made.

As a result of these findings, our institution developed a free mobile application (PulseOxTool, available in most mobile app stores) and a companion website (www.PulseOxTool.org) to aid healthcare personnel in screening for CCHD using pulse oximetry. These tools are widely available for anyone to use. In addition, public health agencies are experimenting with ways in which electronic medical records may facilitate coordination of screening for CCHD.[8] Specialized pulse oximetry equipment that guides screening for CCHD and is automatically linked to the medical record and/or health department may be ideal. Future studies assessing the impact of these tools or other computer-based tools in actual practice are warranted.

In screening for CCHD using pulse oximetry, we found that human interpretation of a proposed paper algorithm is prone to error, and a computer-based tool can improve the accuracy of interpretation of testing results. A free mobile application and companion website have been developed to help improve the quality of screening for CCHD in actual practice. ■

We wish to acknowledge Sushil Bansal and Shalabh Bansal for their help in the development of the pilot website that was used for this project.

Submitted for publication May 20, 2013; last revision received Aug 2, 2013; accepted Aug 21, 2013.

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50 Years Ago in *The Journal of Pediatrics*

Disaccharidase Deficiencies with Steatorrhea

Lifshitz F, Holman GH. J Pediatr 1964;64:34-44

Fifty years ago, Lifshitz and Holman described a 7-week-old infant with protracted diarrhea and failure to thrive. The stools were acidic with positive reducing substances and a high fecal fat content. The diarrhea resolved, and the infant gained weight when given feeds devoid of all starches and disaccharides with glucose as the only carbohydrate source. This was also accompanied by decrease in fecal fat loss. Postulating deficiency of intestinal disaccharidases, they embarked on an elaborate series of investigations that involved administration of various sugars while measuring change in blood glucose as a means of determining digestion and absorption. They concluded the infant had lactase, sucrose, and isomaltase deficiency. Intestinal biopsy obtained during laparotomy demonstrated "blunted, short villi." A vague family history of similar problems in infancy lead them to conclude the infant had congenital absence of these disaccharidases.

In retrospect, it is unclear whether the infant had congenital disaccharidase deficiencies or deficiencies secondary to intestinal mucosal damage associated with protracted diarrhea and severe malnutrition. The excessive fecal fat loss was a novel finding. Since then, excessive fecal fat loss has been shown to be frequent in infants with diarrhea, and stool fat output increases with increasing stool volume.[1] Today, we are able to determine disaccharidase activity from intestinal biopsies obtained during endoscopy. Although relatively rare, congenital deficiencies of lactase and sucrose/isomaltase are now well recognized. Of note is that typically these conditions have normal small intestinal mucosal architecture, unlike the findings in the case described. Other rare congenital causes of diarrhea such as tufting enteropathy and microvillus inclusion disease are also now identifiable. It is unlikely the infant described had any of these conditions as they do not typically respond to dietary manipulation. Without knowing the long-term outcome of this case, we will never know whether this was truly a congenital deficiency or one capable of complete recovery with adequate nutritional rehabilitation. Nevertheless, Lifshitz and Holman were pioneers in identifying disaccharidase deficiencies in an era before these could easily be measured from mucosal tissue samples.

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http://dx.doi.org/10.1016/j.jpeds.2013.07.038

Reference

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Pulse Oximetry Screening for Congenital Heart Disease

Participant ID: _____

Occupation: _____

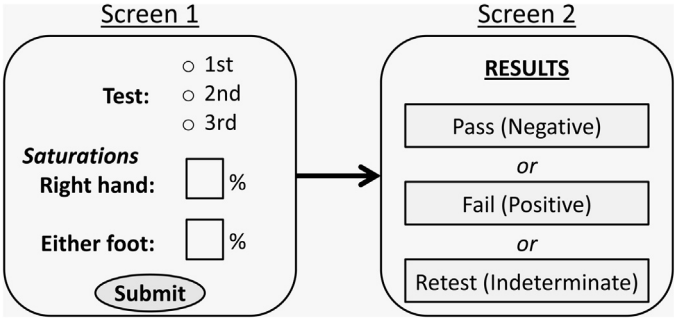
Computer: First / Second

Scenario	Test	Right Hand	Either Foot	Pass (Negative)	Fail (Positive)	Retest (Indeterminate)
1	1st	98%	99%			
2	1st	99%	95%			
3	3rd	96%	94%			
4	1st	98%	90%			
5	1st	89%	92%			
6	3rd	94%	93%			
7	2nd	97%	96%			
8	1st	93%	97%			
9	3rd	100%	95%			
10	1st	96%	95%			
11	1st	97%	95%			
12	1st	95%	99%			
13	3rd	96%	94%			
14	1st	90%	96%			
15	1st	98%	88%			
16	3rd	92%	93%			
17	2nd	95%	96%			
18	1st	98%	94%			
19	3rd	96%	100%			
20	1st	99%	97%			

Follow-Up Questions:

1. How easy to use do you think the **paper** pulse oximetry algorithm is:
   Very easy Easy Difficult Very Difficult
2. How easy to use do you think the **computer** pulse oximetry algorithm is:
   Very easy Easy Difficult Very Difficult
3. How likely are you to use the computer tool if offered:
   Very likely Likely Not likely Not at all likely
4. I would prefer to use (circle one): Paper Computer
5. Comments:

Appendix 1. 20 mock scenarios and the subsequent survey questions.



Appendix 2. Computer tool used for this study. Participants were asked to input the relevant data from the mock scenario into the online tool and then to press a button to submit the data. The computer program then used the algorithm to interpret the submitted data and display the recommended interpretation. Participants would then repeat this process for each scenario using the computer tool.