Comparison Noninvasive Hemoglobin and Invasive Spun Hematocrit Testing in WIC Participants

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Introduction

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is funded by United States Department of Agriculture and provides Federal grants to States for nutrition assessments, health care referrals, nutrition education, and supplemental foods for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age five who are found to be at nutritional risk.

Two major types of nutrition risk are recognized for WIC eligibility:

- Medically-based risks such as anemia, underweight, overweight, history of pregnancy complications, or poor pregnancy outcomes.
- Dietary risks, such as failure to meet the dietary guidelines or inappropriate nutrition practices.

Nutrition risk is determined by a health professional such as a physician, nutritionist, or nurse and is based on Federal guidelines.

Iron deficiency anemia (IDA) is by far the most common cause of anemia in children and women of childbearing age. It may be caused by a diet low in iron, insufficient assimilation of iron from the diet, increased iron requirements due to growth or pregnancy, or blood loss. Anemia can impair energy metabolism, temperature regulation, immune function, and work performance. Anemia during pregnancy may increase the risk of prematurity, poor maternal weight gain, low birth weight, and infant mortality. In infants and children, even mild anemia may delay mental and motor development. The risk increases with the duration and severity of anemia, and early damages are unlikely to be reversed through later therapy.

Hemoglobin measurement is an essential component of anemia screening for nutrition consultation at WIC centers. The most common methods used to measure hemoglobin in a WIC setting require an invasive, finger-stick blood sample for analysis on a point-of-care device or by spun hematocrit. Both methods require an invasive capillary blood sample, e.g. finger-stick collection procedure. These tests can be painful for the participant, expose the staff to human blood, and require training and quality control to ensure appropriate utilization and adherence to CLIA standards. In contrast, a new noninvasive spot-check hemoglobin device (Pronto, Masimo Corporation, Irvine, CA) provides a hemoglobin measurement (SpHb®) using a sensor that shines multi-wavelengths of light through a finger.

Study Objective

The objective of this study was to compare the clinical utility of Pronto to the current invasive point-of-care spun hematocrit testing methodology. Comparisons included:

- Feasibility of use in the WIC setting.
- Ability to identify participants at risk of anemia.
- Comparison of variance in test results between the Pronto and spun hematocrit.
- Clinician and participant satisfaction with testing methodology.

Methods

During a 4 day period, participants presenting to the Amarillo, Texas WIC Center were consented and screened for hematocrit/hemoglobin using both the spun hematocrit method and the noninvasive Pronto device with a reusable finger clip sensor (rev. G, Masimo Corporation, Irvine, CA). The Pronto is indicated for use for patients of 10 kgs or greater (22 lbs.), but attempts were made to screen all participants including those less than 22 lbs. Since the Pronto device is noninvasive, safety was not an issue. Finger sticks and spun hematocrit measurements were conducted according to the standard operating procedures of the center. The Pronto and spun hematocrit were performed within 2 minutes of each other from the same hand while participants were quiet and sitting upright. The duration of each procedure from start to finish was recorded. A survey measuring participant satisfaction was administered after the completion of both tests. In addition, a staff satisfaction survey was administered at the end of the trial.

Results: Feasibility Among Population Screened

A total of 115 subjects were enrolled. Of the 115 subjects, 75 were children age 0-4 yrs (both boys and girls), 38 were women age 18-40 yrs., and 2 adolescent females, age 15-17 yrs. Spun hematocrit determination was obtained on 100% (115) of the participants. The Pronto device was able to obtain a measurement on 101 (88%) of the participants. Pronto was unable to obtain a measurement, classified as a test incomplete, on 14 participants, of which 11 (79%) were under 24 months. Nine (64%) were due to movement and 5 (36%) to low perfusion.

Pronto Performance Summary

Participants		Measurements	
Classification	**Number**	**Complete**	**Incomplete**
Women	40 (35%)	40 (100%)	0 (0%)
Children (1-5 years)	67 (58%)	58 (87%)	9 (13%)
Infant (<1 year)	8 (7%)	3 (38%)	5 (62%)
Total	**115 (88%)**	**101 (88%)**	**14 (12%)**

*The Pronto device is indicated for use for patients of 10kgs or greater (22lbs.).

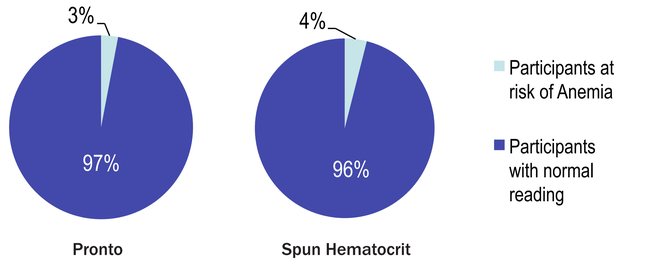
Average Time Per Test

Pronto = 2:04 minutes

Spun Hematocrit = 3:54 minutes

Results: Comparison of Test Methods to Identify Those at Anemic Risk

One hundred and one subjects had paired hematocrit and Pronto results. Based on the spun hematocrit results, 4 out of 101 (4%) participants were at risk of anemia (indicated as hematocrit of less than 33%). Based on the Pronto results, 3 out of 101 (3%) participants were at risk of anemia (indicated as SpHb of less than 11 g/dL). Noninvasive hemoglobin testing with the Pronto identified a similar proportion of participants at risk of anemia.



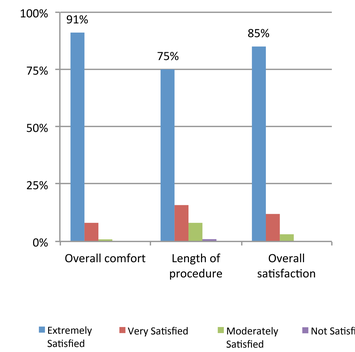
Pronto® by Masimo®

Results: Participant/Staff Satisfaction Survey

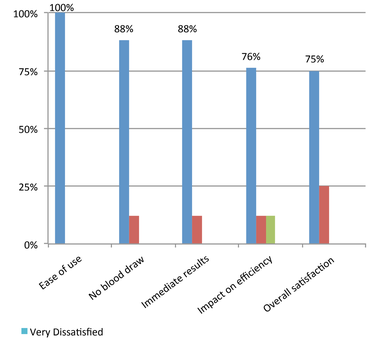
Seventy five participants completed the participant survey. Ninety five percent of the participants responded with “very satisfied” or “extremely satisfied” (4 or 5) to questions rating their comfort and satisfaction with the Pronto procedure. Ninety nine percent of participants responded “Yes” to the question, “Would you welcome the Pronto procedure on your next visit?”

Eight WIC staff clinicians completed the satisfaction surveys. On a scale of 1-5, (1 being “Not at all Satisfied” and 5 being “Extremely Satisfied”), 100% of the clinicians indicated that they were very or extremely satisfied with the ease of use, accuracy and time to obtain a measurement of the Pronto device. All surveyed were very or extremely satisfied “overall” with the Pronto and would “recommend the Pronto device to a colleague.”

Participant Satisfaction with the Pronto



Staff Satisfaction with the Pronto



Participant Satisfaction with the Pronto

Staff Satisfaction with the Pronto

Conclusion

Noninvasive hemoglobin measurement with the Pronto device provided fast and easy hemoglobin measurement in the vast majority of WIC participants. The Pronto was able to identify a similar number of participants at risk for anemia compared to the standard measurement method (spun hematocrit), and both clinical staff and WIC clients were very satisfied with the Pronto test procedure. The Pronto may provide a hemoglobin screening method that confers greater patient comfort and staff satisfaction with similar clinical utility compared to the current, invasive screening method.

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*Supplies provided by Masimo Corporation.