Assessment of a non-invasive haemoglobin sensor NBM 200 among pregnant women in rural India

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Abbreviations

Hb- Haemoglobin, SD- Standard deviation

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Abstract

Objective: This study aimed to assess a non-invasive haemoglobin sensor NBM 200 in pregnant women in a rural Indian setting.

Methods: The study population consisted of women between 3 to 5 months of pregnancy, from 33 villages in Tuljapur and Lohara blocks of Osmanabad district, Maharashtra between April 2014 and June 2015. Haemoglobin (Hb) measurements obtained from the non-invasive sensor NBM 200 were compared with measurements obtained from an automated haematology analyser Sysmex XP-100, using the Bland Altman method and Spearman's Rank correlation coefficient. Interclass correlation coefficient (ICC), sensitivity and specificity values were used to assess the anaemia diagnostic accuracy of NBM 200 against the gold standard (Sysmex XP-100).

Results: Data were obtained from 269 pregnant women (median age: 21 years, Interquartile range: 19 to 23 years). Haemoglobin levels estimated by the Sysmex XP-100 analyser ranged from 5.5 g/dL to 14.1 g/dL (mean: 10.0 g/dL, standard deviation (SD): 1.28), while measurements obtained from NBM 200 ranged from 9.5 g/dL to 14.6 g/dL (mean: 11.9 g/dL, SD: 1.43). The Spearman's test found a significant, moderately positive correlation between the two methods (r_s= 0.4, p<0.001), ICC was 0.22, and the Bland-Altman analysis showed a mean difference of -1.8 g/dL (95% Confidence interval (CI): -2.06 to -1.71) indicating a systematic overestimation of Hb using the NBM 200. The NBM 200 showed low sensitivity (33.7%; 95% CI: 27.3 - 40.5) but high specificity (91.8%; 95% CI: 81.9 - 97.3) for the diagnosis of anaemia.

Conclusion: Haemoglobin measurements obtained from the NBM 200 were higher with consequent underestimation of anaemia as compared with the gold standard reference method. This limits the use of the NBM 200 as an anaemia diagnostic test in our study population consisting of women during pregnancy.

Keywords: Anaemia, Non-invasive Haemoglobin, NBM 200, Sysmex XP-100, Pregnancy, India.

Introduction

Haemoglobin (Hb) is commonly used to measure anaemia status using an automated haematology analyser [1] but this requires both blood withdrawal and access to laboratory facilities. In developing countries, many individuals, often those with greater health needs, do not have easy access to diagnostic facilities [2]. Recently, the non-invasive haemoglobin sensor NBM 200 was introduced for Hb assessment, which provided an opportunity for anaemia screening at population level in developing countries [1, 2]. The NBM 200 sensor is a non-invasive portable device consisting of a finger probe and a processing unit with digital display. The finger-blood analyser uses occlusion spectrometry to estimate Hb in approximately 60 to 100 seconds [3].

Recent studies conducted to validate NBM 200 mainly involved blood donation centers within hospital settings [4]. There is a strong clinical need to measure Hb levels accurately in settings where laboratory access is not easy, particularly during pregnancy where repeated measurements are required. However, there are no published evidences on the application of non-invasive Hb sensors outside hospital settings for antenatal anaemia screening [2, 4]. Thus it is an important area of research considering the high prevalence of anaemia in women during pregnancy in country like India [5, 6]. Moreover, there is little evidence for the accuracy of non-invasive haemoglobin sensors used in rural community settings. Therefore, the present study aimed to assess non-invasive haemoglobin measurements (using the NBM 200 sensor) against measurements obtained from a gold standard method using an automated haematology analyser (Sysmex XP-100) [7] among pregnant women living in rural India.

Materials and Methods

A cross-sectional study was conducted in 33 villages from Tuljapur and Lohara blocks, Osmanabad district, in the Indian state of Maharashtra with a catchment population of approximately 64,000 individuals. The primary aim of the study was to investigate the prevalence and risk factors of anaemia in pregnant women; this paper reports on a secondary aim which was to validate the use of the non-invasive Hb sensor NBM 200 as a screening test for anaemia in this population. The study population consisted of pregnant women between 3 to 5 months of pregnancy who provided data in the period 24th April 2014 to 30th June 2015. Each participant was recruited after obtaining written consent in the

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presence of a witness and the primary investigator (AA). Trained data assistants obtained the non-invasive haemoglobin measurements in accordance with manufacturer's guidelines for the NBM 200 (Orsense Ltd, Nes-Ziona, Israel). Exclusion criteria were physical deformity of thumb of a non-dominant hand, any injury/ulcerations, localized infection, edema and skin breaks [8]. The gold standard measurement was obtained using a fully automated haematology analyser (Sysmex XP-100, Japan) on a venous blood sample at the haematology laboratory based in the Halo Medical Foundation's (HMF) registered hospital at Andur, Maharashtra [7]. The non-invasive test was conducted in a sitting position in field (either at the participant's home or in village health/nutrition center) followed by blood withdrawal within a 5-minutes interval [9]. For every participant, the non-dominant hand was used for venous blood withdrawal from the median cubital vein and the thumb of the same hand was used to obtain the non-invasive measurement [9]. The venous blood was obtained under an aseptic protocol using a 2-mL disposable sterile syringe. Each participant was asked to wait for 10 minutes after completion of both tests to ensure no adverse effect occurred post blood withdrawal. The blood sample was transferred to a 2-mL vacuum tube containing ethylenediaminetetraacetic acid (EDTA anticoagulant), which was then safely transported in a standard blood carrier container and tested in the HMF laboratory using Sysmex XP-100 within four hours of withdrawal. The analyser was calibrated everyday according to the manufacturer's guidelines and standard laboratory protocol [7].

Hb measurements obtained from each method were used to categorise each participant as having anaemia (Hb < 11 g/dL) or not [10]. We also classified participants as having severe anaemia if their Hb values were less than 7.0 g/dL [10]. Spearman's rank correlation coefficient (r_s) and Interclass correlation coefficient (ICC) was used to assess correlation and accuracy respectively, between the Hb measurements obtained from the two methods. Agreement between two methods was further investigated using the Bland-Altman analysis [11]. The diagnostic accuracy of the NBM 200 was then assessed against the Sysmex XP-100 (the gold standard comparison in our study) [7]. The sensitivity (the proportion of true positives correctly identified by the NBM 200), specificity (the proportion of true negatives correctly predicted by the NBM 200), positive predictive value (PPV) i.e., the proportion of NBM 200 anaemia positive participants for whom the anaemia diagnosis was validated by the Sysmex XP-100, and negative predictive value (NPV) i.e., the proportion of NBM 200 anaemia negative participants who were non anaemic as per the Sysmex XP-100 were estimated. All statistical analyses were conducted using Stata Statistical Software (v13.1, Texas, USA). The study was approved by the Institutional Ethics Committee of Government Medical College of Aurangabad, India (Reference number: Pharma/IEC/GMA/196/2014),

and also by the Nottingham University Medical School Research Ethics Committee (Reference number: E10102013).

Results

We approached 278 eligible pregnant women from 33 villages of Osmanabad district, of which 271 (97.5%) agreed to participate in the study. Due to a technical sensor error, the non-invasive haemoglobin readings of two participants could not be obtained, leaving 269 samples (96.8% of the eligible women) for analysis.

The median age of study participants was 21 years (Interquartile range: 19 to 23 years). The Hb estimated by Sysmex XP-100 (gold standard) ranged from 5.5 g/dL to 14.1 g/dL (mean: 10.0 g/dL, Standard deviation (SD): 1.28), while the Hb estimated by the NBM 200 ranged from 9.5 g/dL to 14.6 g/dL (mean: 11.9 g/dL, SD: 1.43). The Sysmex XP-100 analyser (gold standard) results showed a high prevalence of anaemia (77.3%) in the study population with 5 (1.9%) individuals classified with severe anaemia (Table 1). The NBM 200 sensor measurements classified 27.9% of the study population with anaemia and none with severe anaemia.

The Bland-Altman plot is presented in Figure 1. A comparison of measurements from the two Hb estimation methods yielded a mean difference of -1.8 g/dL (95% Confidence interval (CI): -2.06 to -1.71) suggesting a systematic overestimation of Hb using the NBM 200. In 11.2% cases the NBM 200 yielded Hb measurements that were equal to or marginally higher than the measurements from the Sysmex XP-100. A statistically significant, moderately positive correlation was observed between NBM 200 and Sysmex XP-100 measurements (Spearman's correlation coefficient r_s= 0.4, p<0.001). Diagnostic accuracy for the NBM 200 for anaemia were as follows: sensitivity 33.7% (95% CI: 27.3%, 40.5%), specificity 91.8% (95% CI: 81.9%, 97.3%), positive predictive value 93.3% (95% CI: 85.1%, 97.8%), and negative predictive value 28.9% (95% CI: 22.6%, 35.8%). The ICC was 0.22 (95% CI: -0.08 to 0.47) for an absolute agreement.

Discussion

In this study involving women during pregnancy, we found that haemoglobin measurements obtained from the NBM 200 were generally higher than the measurements obtained from the Sysmex XP-100 (gold standard). Consequently, the NBM 200 grossly underestimated the

anaemia prevalence in our study population (sensitivity of 33.7%). The ICC indicated fair agreement for NBM 200, however we identified possible patient safety concerns with the use of the NBM 200, considering all the severe anaemia cases in our study participants were misclassified as having moderate anaemia and would not have received appropriate clinical intervention had this method alone been used (Table 1).

Our study has many strengths; to our knowledge it is the first where prospectively collected data are presented from a large representative population of pregnant women in a rural community setting [4]. The study population was drawn from marginalised and difficult to access areas where comparatively few healthcare facilities are available, and thus evaluating non-invasive portable technology in geographically remote areas is highly important. Secondly, our study recorded good response rate (96.8%), with only seven eligible women declining to participate. Lastly, the non-invasive readings were obtained in accordance with the manufacturer's guidelines, and none of our subjects had thumb deformity, infection, ulcerations, edema, or skin colourants such as henna (locally known as Mehndi) [12]. However, a technical failure of the non-invasive sensor occurred twice during the study, which delayed data collection, and caused the loss of two samples as mentioned before.

Our study findings are in agreement with those from a study conducted at a blood center in Seoul, Korea by Kim et al. [13] where the NBM 200 Hb measurements tended to be higher than the LH500 automated hematology analyser estimates (Beckman Coulter Inc., Brea, CA, USA). The sensitivity (38.6%) and specificity (93.6%) analyses were very similar to our study and indicated that the NBM 200 failed to detect more than half of the ineligible blood donors. Though the correlation between these two techniques was satisfactory (r_s 0.86), the strong agreement may not be the criteria for donor selection, as accurate blood parameters are prerequisites to prevent any ineligible donor selection. Similarly, an Italian study (n= 3995 donors) showed a low sensitivity using NBM 200 (36.03% in men group and 45.76% among women) on comparison with the gold standard Beckman Coulter's AcT-5 diff AL (Beckman Coulter Inc., Brea, CA, USA) [14]. However, our findings are in contrast to a recent study involving blood donors (n= 485, 94% men) from North India that reported a 71.7% sensitivity for the NBM 200 when compared with the Sysmex KX-21 analyser (Sysmex Corporation, Kobe, Japan) (Table 2) [5]. Despite the high sensitivity, the Bland Altman limits of agreement were wide (Upper limit of agreement: 2.09 and Lower limit of agreement: -3.39) with poor correlation (r_s= 0.43) between the two Hb estimation methods. About 45.5% of ineligible donors were not detected in the Indian study [5], similar to the

study by Kim et al [13]. A second study from Northwest India [6] involving 200 blood donors (96% men) showed high sensitivity (96.36%) when compared with the Sysmex KX-21 analyser (Sysmex America Inc., Lincolnshire). The results by NBM 200 showed wide variation on assessing correlation with the gold standard; however the mean of difference was non-significant [6]. Belardinelli and colleagues [15] also reported high sensitivity (98%) and specificity (97%) in a similar study population. It is worth noting however, that all the patients in their study had Hb values above 13 g/dL (as ascertained using the Beckman Coulter AcT-5 diff cell counter) and unlikely to be representative of the general population.

A study [8] involving pregnant women from Israel (n=63) reported Hb in the range 6.9 g/dL to 13.9 g/dL by the gold standard (LH750 analyser, Beckman Coulter Inc., Brea, CA, USA), which was lower than the range reported by the NBM 200 (7.7 g/dL to 14 g/dL). The Bland Altman analysis showed wide limits of agreement (-1.59 to 1.79) with a standard deviation error of 0.86 g/dL. The study concluded that the sensor measures haemoglobin accurately mainly based on a strong correlation, however, correlation measures association and not agreement [11, 13]. Secondly, the range of Hb values obtained by the gold standard and NBM 200 clearly indicate that the NBM 200 missed some severe anaemia cases similar to our experience [8]. Lastly, the study involved pregnant women from all trimesters (gestational age: average 35.9 weeks, range 13 to 41 weeks), where Hb is likely to vary [9], while our findings are based on larger sample size (n=269) between a fixed gestational period (3 to 5 months of pregnancy) and included a more detailed diagnostic analysis reporting the Bland Altman agreement method, sensitivity, specificity, NPV, PPV and correlation analyses.

Previously published studies of the NBM 200 sensor (Table 2) have been mostly conducted in prospective blood donors [5, 6, 12, 14, 15], in whom Hb is likely to be higher than the general population. Moreover, the two Indian studies outlined earlier, had fewer than 7% women participants [5, 6]. A report from Indian National Family Health Survey 2005-06 showed a 24% anaemia prevalence in men (aged 15-49 years), which was much lower than in women (55% prevalence, 15-49 years) [16]. Based on our results, the NBM 200 underestimates anaemia prevalence; therefore, the validation of the non-invasive technology predominantly in male blood donors could explain the different findings. The study by Singh et al. had a prevalence of 2.3% anaemic cases identified by the gold standard [5], and the study by Malukani et al. had only 17% anaemic cases [6] as compared to our study with 77.3% anaemic cases, suggesting sampling variability [4]. Studies from Italy, Germany and France involved fairly equal number of men and women reporting to blood donation centers,

but anaemia prevalence is much lower in these countries compared to India. The German study reported a mean haemoglobin value of 13.4 g/dL (SD 0.93) in women (using gold standard, Sysmex KX-21) [12], while in our study settings in rural India mean haemoglobin was 10.0 g/dL (using gold standard, Sysmex XP-100). Similarly, the mean haemoglobin in the French study was 13.2 g/dL (95% CI: 11.9, 14.3) [1] and in the Italian study the boxplot indicated a mean Hb of 14.0 g/dL [15]. A systematic review and meta-analysis by Kim et al. [4] of non-invasive Hb sensor technologies (Radical 7, NBM 200, Pronto 7 and NBM 200MP) found that the pooled mean difference and SD were 0.10, + - 1.37 g/dL respectively (95% CI: -2.59, 2.80, I^2 = 95.9% for mean difference and I^2 =95.0% for SD). The review concluded that because of the wide limits of agreement with reference methods, clinical decisions based on non-invasive devices should be made cautiously. All studies included in the review were hospital-based, and none of the studies were from developing countries where anaemia prevalence is typically much higher.

Conclusions and implications

This is the first study conducted in a rural community setting where a representative sample of pregnant women was assessed. Our measurements were obtained in the field during a household survey which provided a unique opportunity to test the non-invasive technology in rural areas, where diagnostic facilities are limited. Globally, anaemia is a major public health issue affecting pregnant women particularly in developing country like India. Laboratory investigation of anaemia requires established infrastructure and the facility to transport blood samples. A portable non-invasive sensor that provides rapid results could provide opportunities for population level anaemia screening; however, the technology needs to be improved substantially to provide accurate readings in line with the accepted gold standard, before it can be implemented in a rural Indian population. As most studies, including our own, suggest a systematic overestimation of Hb values by the NBM 200, it may be possible for the manufacturer to improve the performance by recalibrating the sensor or algorithms that process the data collected. If the melanin content of subjects is demonstrated to interfere with Hb readings, then this would need further consideration. In future field-based research in developing countries following improvements to the sensor is required, before advocating the adoption of non-invasive technology for haemoglobin measurement and anaemia diagnosis.

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Figure legends

Figure 1 Bland-Altman Analysis of Sysmex XP-100 and NBM 200 Haemoglobin measurements

Footnote for figure 1:
* ULA: Upper limit of agreement, LLA: Lower limit of agreement
LLA -4.79 g/dL and ULA 1.01 g/dL, Mean difference -1.8 g/dL (95% CI: -2.06 to -1.71).

Table 1 Cases of severe anaemia which were measured as moderate anaemia by the non-invasive sensor

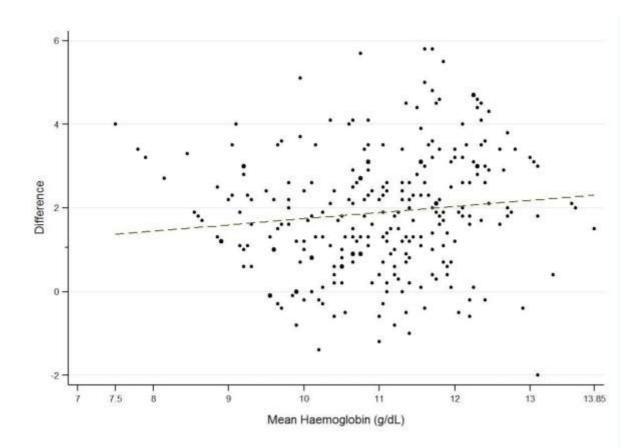| No	Hb measurement by Sysmex XP-100 haematology analyser	Hb measurement by NBM 200 sensor for the same participant
1	5.5 g/dL	9.5 g/dL
2	6.1 g/dL	9.5 g/dL
3	6.3 g/dL	9.5 g/dL
4	6.8 g/dL	10.1 g/dL
5	6.8 g/dL	9.5 g/dL

Figure 1: Bland Altman Plot of NBM200 and Sysmex XP-100

Table 2 Published studies conducted to validate NBM 200 sensor

Ref	First author, year of publication	Study settings	Country, population and sample size	Method of comparison and gold standard used	NBM 200 performance
1	Gayat Etienne et al, 2012	Emergency department, Foch university hospital, Suresnes, France.	France Patients reporting to emergency department n=569 and for NBM 200 n= 297 (men 157 and women 140) Males 52.9% Females 47.1% Data analysed for 270 patients.	Descriptive data, student t test, Bland Altman analysis, Intra-class correlation, Multivariate linear regression to identify variables associated with bias. ADVIA 2120 (Siemens Medical Solutions Diagnostics, Zurich, Switzerland).	Bias: 0.21 g/dL (95% CI: 0.02, 0.39) Bland Altman analysis Upper limit of agreement: 3.42 g/dL (95% CI: 3.10, 3.74) Lower limit of agreement: -3.01 g/dL (95% CI: -3.32, -2.69) Intra-class correlation coefficient: 0.69 (95% CI: 0.62, 0.75) Coefficient of variation (CV): 5.9% True values of haemoglobin and perfusion index were independently associated with NBM 200. Despite the limited bias, wide level of agreement was found, thus clinical usefulness is debatable.
5	Singh Abhay et al, 2015	Blood donation center in tertiary care institute, India.	India Blood donors n= 534, and 485 included in the analysis for NBM 200 (men 455, women 30) n= 485 Males 94% Females 6%	Bland Altman analysis, intra-class correlation coefficient, Specificity, Sensitivity, Negative predictive value (NPV) and Positive predictive value (PPV). Sysmex KX-21 (Sysmex Corporation, Kobe, Japan).	Mean Hb by NBM 200:14.8 g/dL Mean Hb by the gold standard: 14.1 g/dL SD for NBM 200 > 2.0 g/dL, on comparing with gold standard. Bland Altman Agreement ULA: 2.09 g/dL (95% CI: 1.88, 2.30) LLA : - 3.39 g/dL (95% CI : - 3.61, - 3.19) Bias: -0.66 g/dL (95% CI: -0.78, -0.53) Sensitivity 71.7%, Specificity 79.5%, NPV 95.8%, PPV 30.2%

					Intra-class correlation: 0.43 (95% CI: 0.27, 0.55)

NBM 200 did not detect 45.5% of ineligible donors.

NBM 200 has benefit of pain elimination but carries a substantial possibility of ineligible donor selection. |
| 6 | Malukani Pankaj et al, 2014 | Blood donation center in tertiary care hospital, Ahmedabad, Gujarat, India. | India
Blood donors

n= 200 (men 192, women 8)

Males 96%
Females 4% | Specificity, Sensitivity, Negative predictive value and Positive predictive value.

Sysmex KX 21 (Sysmex America Inc., Lincolnshire). | Mean Hb by NBM 200: 13.5 g/dL (SD 1.4)

Sensitivity 96.36%, Specificity 91.43%,
NPV 84.21%, PPV 98.15%
Likelihood ratio 8.22

The results by NBM 200 showed wide variation when compared with the gold standard, but the mean of difference was non-significant. |
| 8 | Hadar Eran et al, 2012 | Women's hospital, Rabin Medical center, Petah Tikva, Israel. | Israel
Pregnant women

n= 63

Average age 31.3 years (range 21 to 25)

Average gestational age 35.9 weeks (range 13 to 41 weeks) | Bland Altman analysis

LH750 automated hematology analyser (Beckman Coulter Inc., Brea, CA, USA). | Hb Range obtained by NBM 200: 7.7 g/dL to 14.0 g/dL

SD 0.86 g/dL

Bland Altman Agreement: -1.59 g/dL to 1.79 g/dL

Correlation coefficient: 0.82
Mean absolute error: 0.71 g/dL

Hb Range obtained by gold standard: 6.9 g/dL to 13.9 g/dL

Study demonstrates good correlation with gold standard and NBM 200 measure Hb accurately. |
| 12 | Sergey Ardin et al, 2015 | Blood donation center of the Institute for Transfusion | Germany
Blood donors

Donors age | Bland Altman analysis

Sysmex KX-21n, | SD for NBM 200 1.14 g/dL, on comparing with gold standard

Bland Altman Agreement: -2.35 g/dL to 2.11 g/dL |

		Medicine of the University Hospital of Cologne, Germany.	mean 36 years (SD 14) n= 351, and for NBM 200 n= 120 (through phase 1 of the study, 78 men and 42 women). Men 65% Women 35%	(Sysmex Europe GmbH, Norderstedt, Germany).	Bias: -0.12 g/dL False rejection of seven donors, however no correspondent unacceptable classification occurred. NBM 200 obtained lower haemoglobin levels in women.
13	Kim Moon Jung et al, 2013	Two blood donation sites affiliated to the Hanmaum Blood center, Gwacheon, Korea.	Korea Blood donors n= 506 (men 291, women 215) Males 57.5% Females 42.4%	Bland Altman analysis, Specificity and Sensitivity. LH500 automated hematology analyser (Beckman Coulter Inc., Brea, CA, USA).	Mean Hb by NBM 200: 14.1 g/dL Intra-class correlation between NBM 200 and LH500: 0.86 NBM 200 Hb < 12.0 g/dL in 37 participants (mean 12.4, SD 1.2) Hb = 12.0 to 12.4 g/dL in 18 participants (mean 12.8, SD 1.1) Hb ≥ 12.5 g/dL in 451 participants (mean 14.4, SD 1.2) Bland Altman plot showed 2 SD difference in haemoglobin estimations between LH500 and NBM 200, Hb > 2.0 g/dL. Whole blood Sensitivity 38.6% (95% CI: 28.1, 50.3) Specificity 93.6% (95% CI: 90.9, 95.5) Apheresis Sensitivity 37.8% (95% CI: 24.1, 53.9) Specificity 94.0% (95% CI: 91.5, 95.8) Out of 70 ineligible donors (Hb < 12.5 g/dL) according to the gold standard (LH500), 43 donors (61.45%) were considered eligible by the NBM 200.

14	Paglirao Pasqualepaolo et al, 2014	Immunohematology and Transfusion Medicine Collection site of S. Orsola Malpighi Hospital, Bologna, Italy.	Italy Blood donors *Data from year 2012* NBM 200 (n) Men= 2945 Women=1021 *Data from year 2013 (n)* NBM 200 Men= 2895 Women=1100	Specificity, Sensitivity, Negative predictive value and Positive predictive value. Donors were classified into fit and unfit sections. Hematocytometry tests as a reference in year 2012. Beckman Coulter's AcT-5 diff AL (Beckman Coulter Inc., Brea, CA, USA) as a gold standard in year 2013.	*2012: NBM 200 and Hematocytometry test* Women (n= 1021) Sensitivity 32.34%, Specificity 95.12%, NPV 85.15% and PPV 61.90% Men (n= 2945) Specificity 98.89%, Sensitivity 14.47% NPV 95.30% and PPV 42.59% *2013: NBM 200 + targeted venous sample (gold standard, Beckman Coulter)* Women (n= 1100) Sensitivity 45.76%, Specificity 99.24%, NPV 90.51% and PPV 92.05% Men (n= 2895) Sensitivity 36.03%, Specificity 99.93%, NPV 96.94% and PPV 96.08% Compared to non-invasive techniques, a venous sample improves donor selection.
15	Belardinelli A et al, 2013	Immunohematology and Transfusion Medicine Collection site of S. Orsola Malpighi Hospital, Bologna, Italy.	Italy Blood donors n= 445 (men 296, women 149) Males 66.5% Females 33.4%	Bland Altman analysis, Specificity and Sensitivity. Beckman Coulter's AcT-5 diff AL (Beckman Coulter Inc., Brea, CA, USA).	Bland Altman Agreement: -1.64 g/dL to 2.21 g/dL Bias: 0.29 g/dL SD: 0.98 g/dL Percentage of donors screened correctly by NBM 200: 88% Sensitivity 98%, Specificity 97% Non-invasive technique does not replicate results of venous sample, and compared to finger-prick (HamoCue), the NBM 200 had low sensitivity and specificity.