Trinidad & Tobago Health Sciences Initiative
HbA1C INITIATIVE

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This author has nothing to disclose

Background

- 350 million persons worldwide currently suffer from Diabetes Mellitus. In Trinidad 12.5% are affected most are undiagnosed
- Chronic complications are preventable with good blood glucose control and large studies like the DCCT and EDIC trials show the importance of HBA1C measurement in this objective.
- Clinical use of HBA1C requires assays on par with DCCT and EDIC standards . This requires high precision and standardization and results should be monitored through proficiency testing (PT)
- In Trinidad and Tobago (T&T) , a developing country no data exists on HBA1C precision and accuracy and there is no nationwide PT program. This brought into question the reliability of current HBA1C assays in use
- Pilot studies were conducted to compare local HBA1C assays to NGSP standards
- This ran as a collaboration between John Hopkins medicine international and the Diabetes Diagnostic Laboratory (DDL) at the University of Missouri

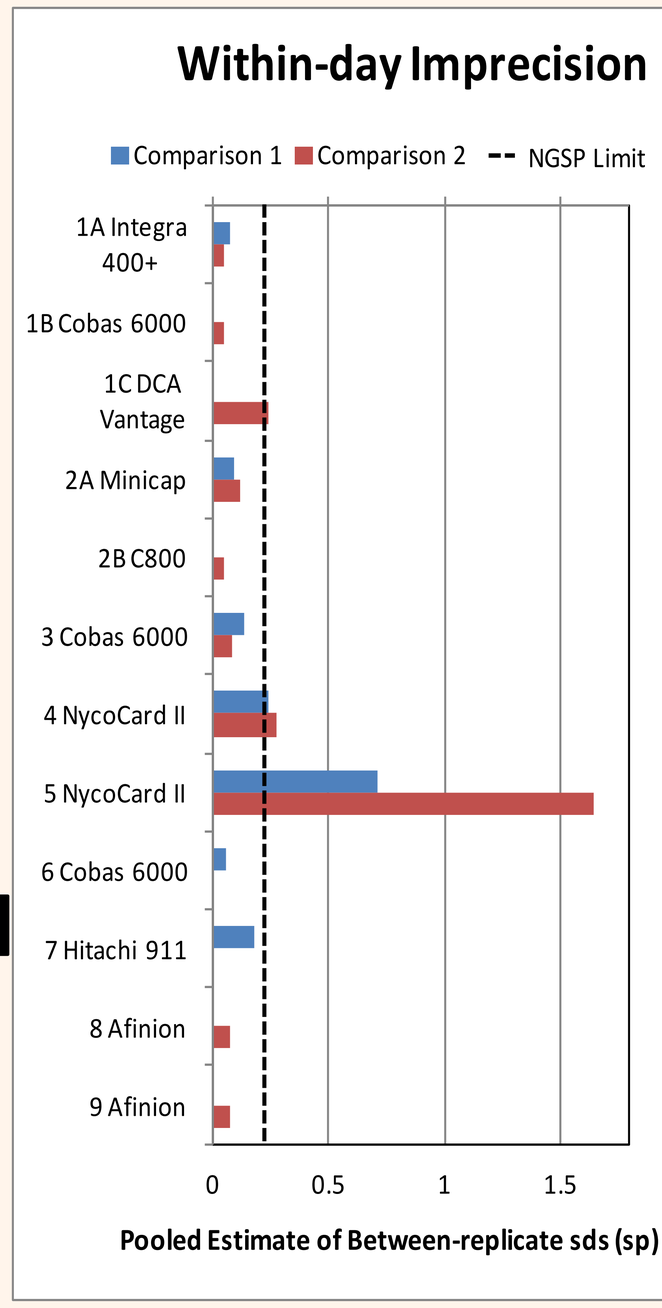
Methods

- For each study, sets of 10 samples containing blinded duplicates were created from five whole blood pools with HbA1c levels between 5.0% and 9.5% HbA1c and shipped to participating laboratories.
- Samples were run and compared to results generated by the NGSP gold standard methods at the DDL
- To assess within-day imprecision, the pooled estimate of the SDs between the duplicates (Sp) was calculated; 0.229 was the acceptable limit based on the current NGSP HbA1c standardization program monitoring criterion.
- To assess accuracy, each laboratory's results were compared to those assigned by NGSP Secondary Reference Laboratories (SRL9: Tosoh G8, SRL3: Trinity ultra2).
- Reports were generated and distributed to all participating labs and discussed in a group setting
- An international expert visited labs to offer assistance in improving HBA1C concordance with NGSP standards

Results

- Six of seven laboratories that participated in the first comparison study also participated in the second
- Nine laboratories participated in the second study, two of which analyzed the samples on two different methods making a total of 11 laboratory/methods
- Methods included in the first comparison study were the Roche Cobas Integra 400+ and Cobas 6000, Alere Nycocard Reader II, Sebia Minicap and Hitachi 911
- The second comparison included the above methods with the exception of the Hitachi 911, plus the Abbott C800 and Alere Afinion
- Laboratory 1A reported results in IFCC% in the first study, these were aligned to NGSP using the master equation [NGSP%=0.915(IFCC%)+2.15, both are shown in the figure]
- Within-day imprecision was within acceptable limits except for the Nycocard II (both laboratories and comparison studies) and DCA Vantage (second comparison)
- **Most results from both laboratories using the Nycocard II were outside of acceptable limits, decreasing the clinical usefulness of the HBA1C measurement.** This practice occurred mainly in public hospitals

Results



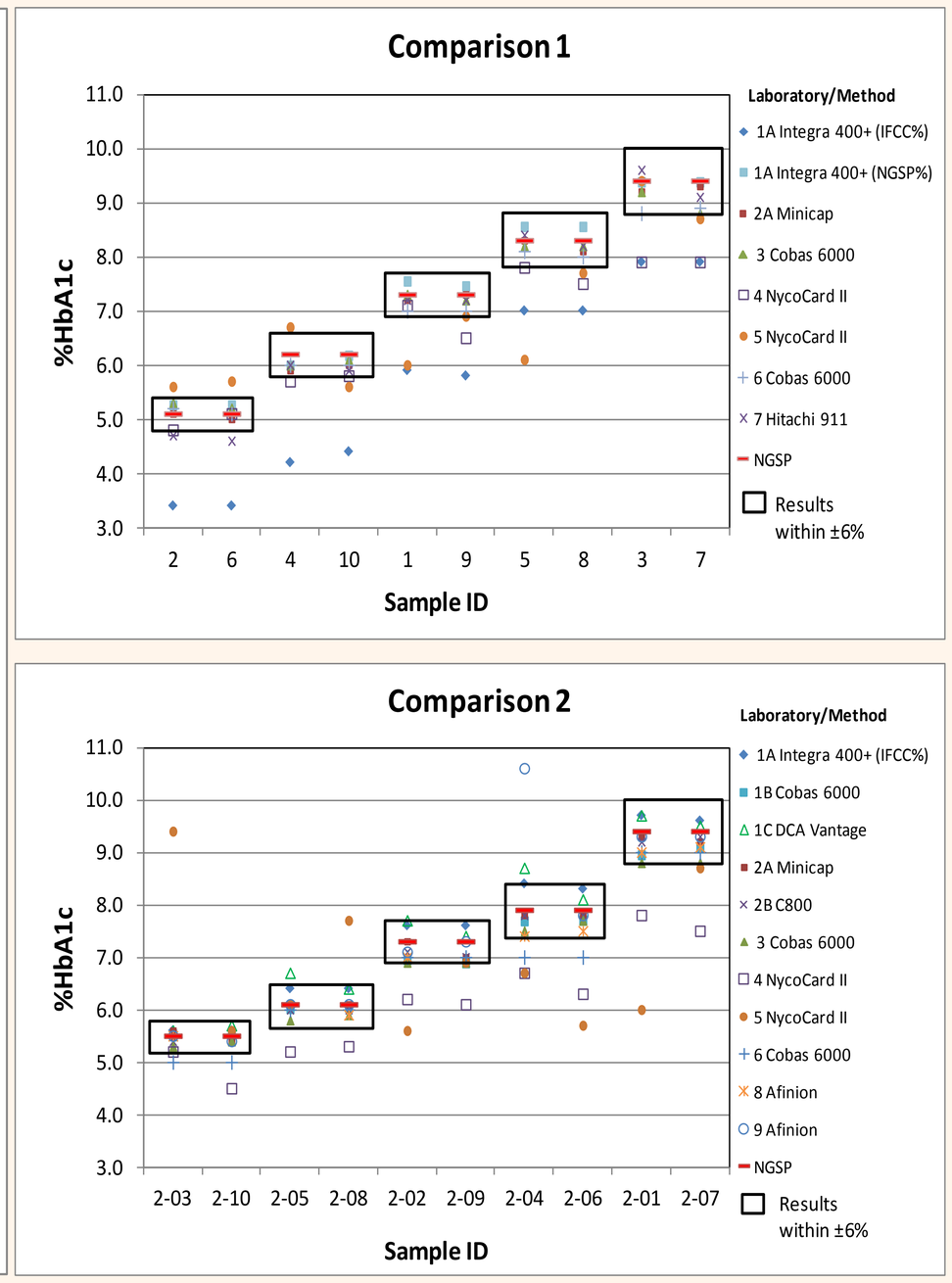


Figure 1: Displays the results for two rounds of comparison testing . Comparison 1 shows results beyond 6% of the NGSP gold standard for the Nycocard II and the Integra 400. Comparison 2 shows the results for the Nycocard II persistently more than 6% outside of the NGSP standard. Note the results for the Integra 400 were due to reporting in IFCC% which was changed prior to comparison 2 testing. Within day imprecision was again highest for the labs using Nycocard II

Conclusions

- Results from most of the participating laboratories showed acceptable comparability to the NGSP and within-laboratory imprecision.
- Although official recommendations are to report HbA1c in both NGSP% and IFCC mmol/mol, individual countries are deciding how results will be reported. Based on recommendations after the first study Laboratory 1A is now reporting NGSP%.
- It is recommended that the laboratories using the Nycocard II switch to a method that demonstrates better performance. However there are financial limitations at these institutions
- Proficiency testing is very important in assuring that HbA1c results are sufficiently accurate to be clinically useful.
- Further PT studies will be performed in Trinidad and Tobago to ensure that the quality of HbA1c testing is sufficient to meet clinical needs.
- Practitioners in developing countries should be aware of the reliability of their HBA1C testing as deviations from international standards will lead to inadvertent errors in patient care

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