**Table 1 Baseline mean HbA1c (%) results from POC and lab in TANDEM study[[1]](#endnote-1)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Variables** |  | **N (%)** | **Mean (95%CI)** |
|  |  |  | **POC HbA1c** | **Lab HbA1c** |
| **Total sample** |  | 1942 (100.00) | 6.00 (5.94, 6.06) | 5.85 (5.80, 5.91) |
|  |  |  |  |  |
| **Sex** | Female | 752 (38.74) | 6.06 (5.96, 6.16) | 5.84 (5.74, 5.95) |
|  | Male | 1189 (61.26) | 5.96 (5.89, 6.03) | 5.86 (5.80, 5.93) |
|  |  |  |  |  |
| **Age group** | <30yrs | 701 (36.10) | 5.74 (5.69, 5.79) | 5.55 (5.51, 5.59) |
|  | 30-39yrs | 444 (22.86) | 5.93 (5.83, 6.03) | 5.66 (5.60, 5.72) |
|  | 40-49yrs | 363 (18.69) | 6.05 (5.89, 6.20) | 6.05 (5.88, 6.22) |
|  | 50-59yrs | 254 (13.08) | 6.46 (6.21, 6.71) | 6.44 (6.19, 6.69) |
|  | 60yrs+ | 180 (9.27) | 6.44 (6.17, 6.71) | 6.31 (6.07, 6.56) |
|  |  |  |  |  |
| **BMI[[2]](#endnote-2)** | Underweight | 714 (36.88) | 5.89 (5.82, 5.97) | 5.77 (5.70, 5.84) |
|  | Normal range | 1055 (54.49) | 5.99 (5.91, 6.08) | 5.85 (5.77, 5.93) |
|  | Overweight | 142 (7.33) | 6.42 (6.14, 6.70) | 6.17 (5.87, 6.47) |
|  | Obese | 25 (1.29) | 6.91 (5.97, 7.85) | 6.75 (5.77, 7.73) |
|  |  |  |  |  |
| **Country** | Indonesia | 734 (37.80) | 6.23 (6.11, 6.35) | 5.96 (5.84, 6.08) |
|  | Peru | 542 (27.91) | 6.14 (6.03, 6.24) | 5.59 (5.51, 5.66) |
|  | Romania | 416 (21.42) | 5.62 (5.54, 5.70) | 5.99 (5.90, 6.08) |
|  | South Africa | 250 (12.87) | 5.64 (5.53, 5.75) | 5.87 (5.77, 5.96) |
|  |  |  |  |  |
| **Anaemia[[3]](#endnote-3)** | Non-anaemia | 1003 (51.67) | 5.96 (5.87, 6.05) | 5.85 (5.76, 5.93) |
|  | Mild anaemia | 557 (28.70) | 6.03 (5.92, 6.13) | 5.92 (5.82, 6.02) |
|  | Moderate anaemia | 354 (18.24) | 6.02 (5.91, 6.14) | 5.82 (5.71, 5.93) |
|  | Severe anaemia | 27 (1.39) | 6.39 (6.02, 6.76) | 5.32 (5.11, 5.54) |
|  |  |  |  |  |
| **Lab HbA1c** | <5.7 | 1123 (57.83) | 5.71 (5.66, 5.76) | 5.34 (5.32, 5.36) |
|  | 5.7-6.4 | 659 (33.93) | 5.91 (5.86, 5.95) | 6.01 (6.00, 6.02) |
|  | 6.5-8.9 | 99 (5.10) | 6.31 (6.12, 6.51) | 6.91 (6.79, 7.02) |
|  | 9+ | 61 (3.14) | 11.81 (11.35, 12.28) | 11.95 (11.44, 12.46) |
|  |  |  |  |  |
| **HIV status** | HIV- | 1654 (95.82) | 6.03 (5.96, 6.09) | 5.88 (5.81, 5.94) |
|  | HIV+ | 72 (4.18) | 5.95 (5.74, 6.16) | 5.66 (5.49, 5.82) |

**Table 2 Intra-individual difference for HbA1c from POC and laboratory sources stratified covariates**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variables** |  | **Mean** | **Intra-individual difference (POC-Lab)****mean-2SD, mean+2SD** | **P value** |
| **Total sample** |  | 0.14 | -1.56, 1.84 | <0.001 |
|  |  |  |  |  |
| **Sex** | Female | 0.21 | -1.48, 1.90 | Ref  |
|  | Male | 0.10 | -1.60, 1.80 | 0.136 |
|  |  |  |  |  |
| **Age group[[4]](#endnote-4)** | <30yrs | 0.19 | -1.36, 1.73 | Ref |
|  | 30-39yrs | 0.27 | -1.79, 2.33 | 0.340 |
|  | 40-49yrs | -0.001 | -1.54, 1.54 | 0.017 |
|  | 50-59yrs | 0.02 | -1.39, 1.43 | 0.010 |
|  | 60yrs+ | 0.13 | -1.71, 1.97 | 0.704 |
|  |  |  |  |  |
| **BMI[[5]](#endnote-5)** | Underweight | 0.12 | -1.33, 1.58 | Ref |
|  | Normal range | 0.14 | -1.70, 1.98 | 0.931 |
|  | Overweight | 0.25 | -1.54, 2.04 | 0.566 |
|  | Obese | 0.16 | -1.03, 1.34 | 0.846 |
|  |  |  |  |  |
| **Country** | Indonesia | 0.26 | -1.10, 1.62 | Ref |
|  | Peru | 0.55 | -1.48, 2.58 | <0.001 |
|  | Romania | -0.37 | -1.47, 0.74 | <0.001 |
|  | South Africa | -0.23 | -1.70, 1.25 | <0.001 |
|  |  |  |  |  |
| **Anaemia[[6]](#endnote-6)** | Non-anaemia | 0.12 | -1.58, 1.82 | Ref |
|  | Mild anaemia | 0.11 | -1.55, 1.78 | 0.920 |
|  | Moderate anaemia | 0.20 | -1.45, 1.85 | 0.523 |
|  | Severe anaemia | 1.07 | -0.93, 3.06 | 0.038 |
|  |  |  |  |  |
| **Lab HbA1c** | <5.7 | 0.37 | -1.33, 2.07 | Ref |
|  | 5.7-6.4 | -0.11 | -1.32, 1.11 | 0.014 |
|  | 6.5-8.9 | -0.60 | -2.16, 0.97 | 0.011 |
|  | 9+ | -0.13 | -3.09, 2.82 | 0.020 |
|  |  |  |  |  |
| **HIV status** | HIV- | 0.15 | -1.43, 1.73 | Ref |
|  | HIV+ | 0.30 | -1.34, 1.93 | 0.940 |

**Table 3 Error grid analysis zones and clinical interpretation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Zone #** | **Definition**  | **Comparison with reference standard**  | **N (%)** | **Clinical interpretation** |
| **A**  | POC<6.5 & Lab<6.5Or Lab-6%<POC< Lab+6% | POC deviates from reference by ≤6% or both values are <6.5 | 1660 (85.5)(1574 HbA1c<6.5 in both POC and Lab results; 86 POC values deviates from Lab results by less than 6%) | A: POC and reference value both <6.5, or POC values deviates from reference values by ≤6% |
| **B1** | POC> Lab+6%  | POC deviates from reference by >6% | 12 (0.6) | B1 and B2: POC deviates from reference by >6%, but would lead to no treatment or no erroneous treatment i.e. does not cross diagnostic cut-points |
| **B2** | POC< Lab-6% | POC deviates from reference by >6% | 67 (3.5) |
| **C1** | POC≥9\* andLab≥6.5 | Overestimation  | 1 (0.1) | C1: poor glycaemic control was identified instead of moderate control |
| **C2** | POC<6.5 and8<Lab<9 | Underestimation  | 2 (0.1) | C2: tight glycaemic control was identified instead of moderate control |
| **D1** | 6.5≤POC<9 and Lab<6.5 | Overestimation  | 188 (9.7) | D1: moderate glycaemic control was identified instead of normoglycaemia |
| **D2** | 6.5≤POC<9 andLab≥13 | Underestimation  | 0 (0) | D2: moderate glycaemic control was identified instead of tight glycaemic control |
| **E1** | POC≥9 and Lab<6.5 | Overestimation  | 11 (0.6) | E1 poor glycaemic control was identified instead of normoglycaemia  |
| **E2** | POC<6.5 andLab≥9 | Underestimation  | 1 (0.05) | E2 normoglycaemia was identified instead of poor glycaemic control |
| **Total**  |  |  | 1942 (100) |  |

\*the stringent cut off of 9% is used as an indicator for poor control. This is based on the level of hyperglycaemia at which TB outcomes are thought to worsen

# See Figure 1 below for graphical representation of the Zones.



**Figure 1. Error grid demonstrating agreement between the laboratory and POC HbA1c measurement**

1. Participant numbers reported here vary slightly from some other TANDEM consortium analyses owing to minor differences in inclusion criteria and/or recruitment period [↑](#endnote-ref-1)
2. Underweight: <18.5 kg/m2; normal range: 18.5-24.9 kg/m2; overweight: 25.0-29.9 kg/m2; obese: ≥30.0 kg/m2. [↑](#endnote-ref-2)
3. Anaemia categories were defined according to WHO. Among non-pregnant women (>15 years) non-anaemia defined as haemoglobin levels >120g/L, mild anaemia defined as 110-119g/L, moderate anaemia was defined as 80-109g/L, and severe anaemia was defined as <80g/L; among men, non-anaemia defined as >130g/L, mild anaemia was defined as 110-129g/L, moderate anaemia defined as 80-109g/L, and severe anaemia defined as <80g/L. Among women, there were five people pregnant and their anaemia level was defined differently as below: non-anaemia >110g/L, mild anaemia is 100-109g/L, moderate anaemia is 70-99g/L, and severe anaemia is <70g/L. [↑](#endnote-ref-3)
4. Wald test was used to test overall differences across all categories; P>0.100 for all tested variables except for country (P<0.001) and Lab HbA1c groups (P=0.035). [↑](#endnote-ref-4)
5. Underweight: <18.5 kg/m2; normal range: 18.5-24.9 kg/m2; overweight: 25.0-29.9 kg/m2; obese: ≥30.0 kg/m2. [↑](#endnote-ref-5)
6. Anaemia categories were defined according to WHO. Among non-pregnant women (>15 years) non-anaemia defined as haemoglobin levels >120g/L, mild anaemia defined as 110-119g/L, moderate anaemia was defined as 80-109g/L, and severe anaemia was defined as <80g/L; among men, non-anaemia defined as >130g/L, mild anaemia was defined as 110-129g/L, moderate anaemia defined as 80-109g/L, and severe anaemia defined as <80g/L. Among women, there were five people pregnant and their anaemia level was defined differently as below: non-anaemia >110g/L, mild anaemia is 100-109g/L, moderate anaemia is 70-99g/L, and severe anaemia is <70g/L. [↑](#endnote-ref-6)