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RESEARCH LETTER

Erroneous inflation of diabetes prevalence: Are there global implications?

Highlights
- Incorrect glucose cut-off points were applied to the Fiji 2011, Samoa 2013, and Tonga 2012 STEPS surveys. This doubled the actual T2DM prevalences compared to using the correct glucose cut-off points.
- The errors occurred due to modern glucose meters producing measurements in plasma-equivalent concentrations from whole blood samples. The incorrect whole blood glucose cut-off (≥6.1mmol/L) was applied instead of the correct plasma glucose cut-off (≥7.0mmol/L).
- This error likely affects other Pacific states, and may have global ramifications.

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In several Pacific Island countries, recent World Health Organization (WHO) STEPwise approach to Surveillance (STEPS) reports have shown considerably elevated prevalence of type 2 diabetes mellitus (T2DM), and significant increases in prevalence compared with surveys conducted 8–11 years previously, not necessarily with the same methodology. Noteworthy examples include: (i) Fiji, which reported a T2DM prevalence of 16.0 % in 2002,[1] increasing to 29.6 % in 2011[2] (+13.6 percentage points or +7.6 %/5 years; proportional increase +85 % in 9 years); (ii) Samoa, which reported that T2DM prevalence increased from 21.5%[3] to 45.8 %[4] over the period 2002–13 (+24.3 percentage points or +11.0 %/5 years; +113 % in 11 years); and (iii) Tonga, which reported a T2DM increase from 16.4 %[5] to 34.4 %[6] over the period 2004–12 (+18 percentage points or +11.3 %/5 years; +110 % in 8 years).[5] These elevated and relatively recent increases in T2DM prevalence have impacted on public health policy, monitoring, and evaluation, as well as advocacy and program planning in the Pacific region. The STEPS survey reports are widely cited and used as a reference by many organizations and individuals who make decisions based on these data as reported. For example, the cost-effectiveness study of the Package of Essential Non-Communicable Disease (PEN) interventions in Tonga[7] was based on T2DM data from the 2012 Tonga STEPS survey.[6] Because many small Pacific Islands do not have adequate population health surveys, estimates and trends of T2DM prevalence for these countries are often modeled on limited data, sometimes using information from nearby or larger neighbors that do have population risk factor survey data available.[8]

In the present study we examined the above six STEPS surveys, collecting information on the blood specimen, glucose meter, blood glucose concentration, and the T2DM definition used. The prevalence of T2DM was recalculated from unit records using both fasting whole blood glucose (FBG; ≥6.1 mmol/L) and fasting plasma glucose (FPG; ≥7.0 mmol/L) cut-off points.[9] Cases of T2DM also included participants currently taking T2DM medication. Case weights were used to adjust for area of residence, sex, ethnicity (Fiji only), and age to the nearest previous census to improve demographic representativeness (similar to STEPS procedures), and 95 % confidence intervals (CI) were calculated from the SE using the normal approximation of the binomial.

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The point-of-care (POC) glucose meters used in the 2002 Fiji (Accu-Chek Advantage; Roche, Mannheim, Germany),[10] 2002 Samoa (Accutrend GCT; Roche),[11] and 2004 Tonga (Accu-Chek Advantage; Roche)[10] STEPS surveys measured glucose in whole blood and reported the concentration in whole blood. Later surveys, namely the 2011 Fiji (Omnitest Plus; Braun, Melsungen, Germany),[12] 2013 Samoa (Accutrend Plus; Roche),[13] and 2012 Tonga (Accu-Chek Performa; Roche)[14] STEPS surveys, measured blood glucose using POC glucose meters that require a whole blood specimen but report glucose concentrations as equivalent to those in plasma. For these POC glucose meters, the whole blood glucose concentration is multiplied by 1.11 to express the glucose concentration as plasma equivalent, in accordance with recommendations from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), first published in 2001[15] and repeated in 2005.[16]

It is apparent that in recent STEPS surveys in Fiji (2011),[1,2] Samoa (2013)[3,4] and Tonga (2012),[5,6] the incorrect glucose cut-off point was applied, and the T2DM prevalence reported were erroneously inflated to approximately double the actual T2DM prevalence had the correct glucose cut-off point been applied (Table 1; Figure 1). When correct plasma cut-off points are applied, changes in T2DM prevalence over the survey periods for each country are as follows: (i) Fiji, from 16.0 % to 15.6 % (−0.4 percentage points) over 2002–11 (instead of the reported +13.6 percentage points)[17]; (ii) Samoa from 21.5 % to 24.3 % (+2.8 percentage points) over 2002–13 (instead of +24.3 percentage points);[18] and (iii) Tonga, from 22.4 % (including estimated all known T2DM) to

Table 1 Type 2 diabetes mellitus prevalence in adults aged 25–64 years in selected Pacific Island countries using whole blood and plasma glucose cut-off points from STEPwise approach to Surveillance (STEPS)

				T2DM prevalence (%)		
				Reported from STEPS	Re-analysis	
STEPS report	Glucose meter used	Blood sample	Glucose meter output		≥6.1 mmol/L And/or T2DM medication	≥7.0 mmol/L And/or T2DM medication
Fiji						
2002[1]	Accu-Chek Advantage (Roche)	Venous	Whole blood	16.0 (12.9–19.1)	**16.5 (15.9–17.1)**	11.8 (10.4–13.1)
2011[2]	Omnitest Plus (Braun)	Inferred capillary	Plasma	29.6 (26.5–32.6)	30.4 (28.5–32.3)	**15.6 (15.1–16.2)**
Long-term trend 1980–2011: +1.41 % per 5 years*						
Samoa						
2002[3]	Accutrend GCT (Roche)	Capillary	Whole blood	21.5 (19.0–24.0)	**20.7 (18.8–22.6)**	10.8 (9.4–12.3)
2013[4]	Accutrend Plus (Roche)	Inferred capillary	Inferred plasma	45.8 (41.6–50.1)	49.7 (47.2–52.1)	**24.3 (22.2–26.4)**
Long-term trend 1978–2013: +2.57 % per 5 years*						
Tonga					≥6.1 mmol/L only†	≥7.0 mmol/L only†
2004[5]	Accu-Chek Advantage (Roche)	Capillary	Whole blood	16.4 (11.0–21.9)	**16.3 (13.0–19.7)**	9.1 (6.5–11.8)
					And/or T2DM medication	
					22.4‡ (19.3–25.5)	15.2‡ (11.9–18.5)
2012[5]	Accu-Chek Performa (Roche)	Capillary	Plasma	34.4 (31.5–37.3)	35.7 (33.7–37.7)	**19.0 (18.4–19.6)**
Long-term trend 1973–2012: +1.88 % per 5 years*						

Prevalence data show percentage prevalence with 95 % confidence intervals in parentheses.
Correct type 2 diabetes mellitus (T2DM) estimates are bolded.
Definitions of T2DM from STEPS survey reports were as follows: Fiji 2002, fasting blood glucose (FBG) ≥6.1 mmol/L or on T2DM medication or on a special prescribed diet from health worker[1]; Fiji 2011, FBG ≥ 6.1 mmol/L[2]; Samoa 2002, FBG ≥6.1 mmol/L and/or on T2DM medication[3]; Samoa 2013, FBG ≥6.1 mmol/L or on T2DM medication[4]; Tonga 2004, FBG ≥6.1 mmol/L only[5]; Tonga 2012, FBG ≥6.1 mmol/L or told they had T2DM by health worker or currently receiving T2DM medication.[6]
*Corrected T2DM prevalence for Fiji,[17] Samoa,[18] and Tonga.[19]
†The reported 2004 Tonga STEPS survey did not include participants taking T2DM medication.
‡Estimated for 2004 Tonga STEPS survey by logistic regression derived from 2012 Tonga STEPS where T2DM (FPG ≥7.0 mmol/L and/or on T2DM medication) was modeled with fasting plasma glucose, age, and body mass index for each gender.

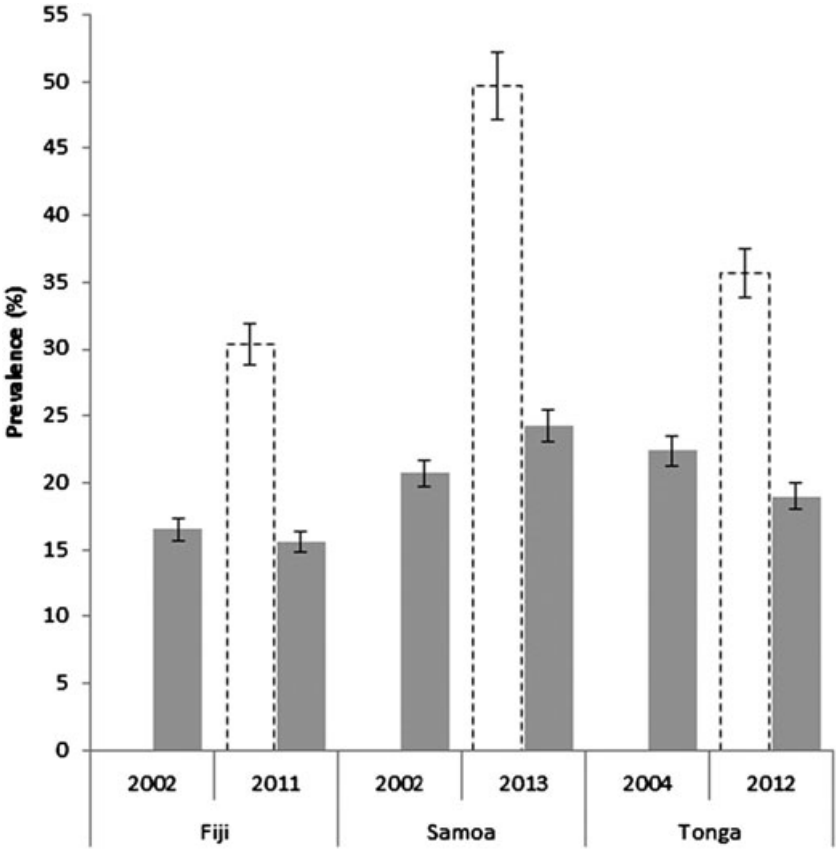

Figure 1 Comparison of the prevalence of type 2 diabetes mellitus (T2DM) in adults aged 25–64 years in selected Pacific Island countries using whole blood and plasma glucose cut-off points. Unit records of STEPwise approach to Surveillance (STEPS) surveys obtained from Fiji, Samoa, and Tonga Ministries of Health; T2DM prevalence recalculated using whole blood and plasma cut-off points. Shaded bars indicate T2DM prevalence based on correct glucose cut-off points for the glucose meter used (fasting blood glucose [FBG] ≥6.1 mmol/L for early surveys[1,3,5]; fasting plasma glucose [FPG] ≥7.0 mmol/L for later surveys),[2,4,6] whereas open bars show T2DM prevalence based on incorrect glucose cut-off points (FPG ≥6.1 mmol/L for later surveys).[2,4,6]

19.0 % (−3.4 percentage points) over 2004–12 (instead of +18 percentage points).[19]

Some of the T2DM prevalence rates reported from other Pacific Island STEPS surveys[20] require further scrutiny where T2DM prevalence appears inordinately high and/or a considerable increase in prevalence is apparent compared with previous surveys. For example, the eightfold increase in reported T2DM prevalence in Vanuatu from 2.8 % in 1998 to 21.2 % in 2011–12[21] appears to be unusually high in a country where obesity levels, the main T2DM risk factor, are relatively low for the region (19 %). Although the glucose meters used in that survey were not reported, it can be inferred that because the 1998 survey was conducted before the first IFCC recommendation, and the 2011–12 survey was conducted after both 2001 and 2005 IFCC recommendations, the glucose meter used in 1998 would have produced glucose concentrations in whole blood, whereas the glucose meter in 2011–12 would have produced plasma-calibrated glucose concentrations. The T2DM prevalence reported in 2011–12 is likely artefactually inflated because it was reported that T2DM in this survey was defined as a fasting capillary blood glucose concentration ≥ 6.1 mmol/L (and/or on T2DM medication),[21] which is the cut-off for T2DM based on fasting whole blood glucose concentration.

In addition, it is worth noting that data from the STEPS studies are not readily available from WHO and are difficult to obtain from individual countries,[22] so these data are not widely available for scrutiny by researchers and others. There are several other issues related to the quality of STEPS surveys that affect the validity of risk factor and diagnostic estimates that are not covered here.

It is unlikely the calculation errors highlighted by the present study are limited to the Pacific Island region and there may well be wider global ramifications.

Explicit information on calibration of and output from glucose meters should be provided by manufacturers, a better understanding by health workers in the use of POC blood glucose meters and interpretation of their results is required, and accurate calculation T2DM prevalence in population health surveys is needed to improve risk factor surveillance and evaluation. Documentation of glucose meters used in health surveys and diagnostic cut-off points used is also necessary, and checking and recalculation of results is required for surveys in which levels and increases in T2DM prevalence appear suspect.

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Disclosure

None declared.

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