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A Note on the Urgent Need for Consistent Regulation of the Procedure for Determination of Reliable Pre-Diabetes Diagnosis, Namely in The Next Edition of the ISO 15197

Franco Pavese *[1]

[1] Former Research Director in Measurement Science (Metrology) at CNR, Italy

* frpavese@gmail.com

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ABSTRACT

The pre-diabetes range is defined as an A1C higher than 5.7% and lower than 6.5%, a narrow range of only 0.8% wide. Because this range is very critical for the patient's health, accurately determining if blood glucose levels stay below 125 mg/ *in fasting conditions* is essential. This is first assessed through home testing, then confirmed by subsequent professional tests of higher accuracy, until a *sufficient statistic is reached*. Significant dietary changes, already recommended when blood sugar exceeds 100 mg/dL, become even more strict and mandatory when exceeding 125 mg/dL: home testing by the patients becomes daily to determine the necessary insulin dose, as opposed to the less frequent checks originally required for pre-diabetes (typically every 3 days, which are sufficient to *create reliable statistics*).

The Note primarily aims to summarise the lack of clarity that patients typically find in the use of tools and in the instructions provided for performing the above-mentioned tests. Some confusion exists even in the documents supplied with the test devices in the literature and online on this subject matter. Most of these materials do not align with the procedures regulating tests in *measurement science, being that the focus of the Note*.

Even key documents prepared by International Bodies, namely the ISO 15197-2015, are suggested in the Note as urgently requiring more specific information and guidelines, especially in the extremely critical pre-diabetes range (only 25 mg/dL wide), a condition shared by a large number of patients being exempt from the full disease and not classified yet as affected by it—a last stage that they might actually never reach in the rest of their lifetime.

1. Introduction

The pre-diabetes range is defined as an A1C higher than 5.7% and lower than 6.5%: a narrow range only 0.8% wide (25 mg/dL over 125 mg/dL, ≤20% wide). It is a fundamental state shared by a large number of patients being exempt from the full disease and not classified yet as affected by it, in fact a last stage that can never be reached in the rest of their lifetime. On the other hand, checking the possible progress to the final stage is extremely demanding for the patient's life; consequently, ensuring that the glycaemia value remains below 125 mg/dL *in fasting conditions* must be determined with the highest confidence possible. This condition is first assessed through home testing, then it must be confirmed by subsequent professional tests of higher accuracy until reaching *sufficient statistics*. In fact, significant dietary changes, already recommended when blood sugar exceeds 100 mg/dL *with assumption of metformine*, become even more strict and mandatory at that last stage: home testing by the patients becomes daily to determine the necessary insulin dose, as opposed to the less frequent checks originally required for pre-diabetes (typically every 3 days), which are sufficient to *create reliable statistics*. It is therefore critical a detailed procedure specifically recommended for the pre-diabetes, requiring a precision quite higher than the one sufficient for assessing full diabetes levels.

Differently from previous author's papers [1-4], this Note will *not* discuss the quality of the *results* of home-testing, but rather the need for a more correct formulation of the instructions for performing home (but also professional) tests, according to a ISO 15197 Standard *modified* with respect to its present 2015 version. [5]

The discussion of the method changes will be limited to the two more critical steps of the full check procedure recommended for pre-diabetes:

A. The scale of glucose levels in blood *in the* ISO 15197 needing *synchronisation with* the *full* pre-diabetes range, in order to take into specific account *only it*;
B. The need *in the* ISO 15197 to explicitly provide guidelines for true *recalibration* of the tester, by enabling *correction* of the test *measured values*.

A different, more general but also important and sometimes critical, issue involves recommendations for providing a more consistent set of instructions regarding the procedure to follow over time to ensure test validity. In fact, the maximum lifetime validity of a strip batch and the maximum time interval adopted between setup calibrations have been found to differ in the instructions supplied by different manufacturers.

2. Suggested improvements of a revised ISO 15197

A) Synchronizing the scale of glucose levels in blood by including the full pre-diabetes range

It is universally agreed that the scale of *levels* of glucose in the blood is summarised in <u>three ranges</u>:

a) Below 100 mg/dL;
b) Between 101 and 125 mg/dL in fasting condition (preferably, or below 140 mg/dL after 2 h from assumption of the glucose test solution determining the so-called glycol profile);
c) Above 140 mg/mL. [a]

On the contrary, in the present ISO 15197-2015 Table 1 [5], the scale is subdivided as indicated:

Table 1: Blood-glucose concentration intervals for measurement repeatability evaluation

Interval
Glucose concentration (mmol/L (mg/dL))
1) 1.7 to 2.8 (30 to 50)
2) 2.9 to 6.1 (*51 to 110*)
3) 6.2 to 8.3 (*111 to 150*)
4) 8.4 to 13.9 (151 to 250)
5) 14.0 to 22.2 (251 to 400)

(*italics* are used for inconsistent boundaries with respect to the above a)—c) subdivision).

In fact, it should be noted that a merely regular interval of 50 mg/dL has been selected in Table 1, which does not match the basic boundary limits of blood glucose concentration: 100 mg/dL, 125 mg/dL, and 140 mg/dL. Of particular importance is the 125 mg/dL *threshold*, considering that the literature consistently indicates TWO test results above that value be sufficient to diagnose patient diabetes, [b] a condition that significantly impacts her life.

Similarly happens in ISO 15197-2015 Table 2 [5] (again *italics* are used here for inconsistent boundaries), and in Table 3 [5] (again *italics* are used here for inconsistent boundaries).

Table 2 — Blood-glucose concentration intervals for intermediate measurement precision evaluation Interval

Glucose concentration (mmol/L (mg/dL))
1) 1.7 to 2.8 (30 to 50)
2) 5.3 to 8.0 (*96 to 144*)
3) 15.5 to 23.3 (280 to 420)

[a] That violates the measurement science rule prescribing a *statistics* in support to decisions. A single anomalous value, in such case, could simply be due to a previous restaurant dinner

[b] That violates the measurement science rule prescribing a *statistics* in support to decisions. A single anomalous value, in such case, could simply be due to a previous restaurant dinner

Table 3: Blood-glucose concentrations of samples for system accuracy evaluation

Bin #; Percentage of samples; % Glucose concentration
mmol/L (mg/dL)
1) 5 ≤ 2.77 (≤ 50)
2) 15 > 2.77 – 4.44 (> 50 – 80)
3) 20 > 4.44 – 6.66 (> *80 – 120*)
4) 30 > 6.66 – 11.10 (> *120* – 200)
5) 15 > 11.10 – 16.65 (> 200 – 300)
6) 10 > 16.65 – 22.20 (> 300 – 400)
7) 5 > 22.20 (> 400).

Table 4: System accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL)

Within ± 0.28 mmol/L	**Within ± 0.56 mmol/L**	**Within ± 0.83 mmol/L**
(Within ± 5 mg/dL)	(Within ± 10 mg/dL)	(Within ± 15 mg/dL)
68/*150* (45.3 %)	105/*150* (70.0 %)	143/150 (95.3 %)

Similarly happens also in Table 4 [5] (again *italics* are used for inconsistent boundaries), where its subdivisions does *not* match the range limits a), b), and c) reported at the beginning of this Section.

Actually, Table 4 should also follow a *different* subdivision rule for system accuracy:
± 10 max up to max 115 mg/dL (8.7% min, critical; 10% at 100 mg/dL, less critical)—better if ± 5 mg/dL up to max 120 mg/dL (4.2% min, 5% at 100 mg/dL less critical). Otherwise, a mere "pass-check" could *override* the critical max value 125 mg/dL since the *uncertainty interval* including the uncertainty value extends from *v-u* to *v+u*.

B–1). The "control solution" is *not* introduced as a "reference material"; instead, it should be
Quite surprisingly, a "nominal value" is *not* associated to the control solution. What the instructions specify is only: "the check with the current strip batch should provide a value *within the range* indicated on the box of strips". However, the latter range typically has a width of 30 mg/dL, e.g., for "range 3" 128-158 mg/dL (middle value, i.e. the "desired value" is 143 mg/dL), thus corresponding to a "sufficient" accuracy of ± 10.5%. This value is twice as large as the (needed) sufficient accuracy indicated above in Section A), Table 4.

The above is thus insufficient and does not match the requirements of a *reference material* that any *control solution* should have, [c] namely in its function of checking the tester *(re)calibration*. [d]

Thus, it should be considered mandatory, instead, to follow the international rules for a *reference material* by supplying: the *nominal* value and its precision, and the indication of the solution lifetime. The latter can currently be confusing: 3 months … of use? (Too short) or 2 years … ? (when not immediately used).

B–2). No (re-)calibration of the test apparatus is presently required, as it should be for the correction of the test readings
The current check requirement is presently limited to a mere "pass-type" test, i.e. simply requiring that tester readings stay *within the strip admitted values range*: this does *not* correspond to a "calibration" of the system, and it also ignores the possible strip-batch offset (as for the 143 mg/dL case indicated above). If a non-pass situation occurs, it is stated by the ISO 15197-2015 that the test system should be replaced. No reading corrections are considered.

However, author's experience indicates that testers often become unstable after about one year of use, and almost invariably with an *increase* in the indicated glucose level up to more than 30%. However, *a re-calibration of the tester is possible*, as demonstrated by author's procedure in, [1–4] based on the strip-batch indicated offset and, on the information, available from *the tester re-calibrations*. Thanks to this, the monthly standard deviation of the *calibrated* glucose values in the pre-diabetic range was *consistently reduced* to within **± 5-8 mg/dL (< 6.5%)** over a period of about 6 years, during which nearly 1000 total tests were conducted (and no one under passing the limit value 125 mg/dL was ever observed)—this result was achieved by using different testers, strips from various suppliers, and control solutions for "range 3," assumed to have a *nominal* concentration of 140 mg/dL (no precision indication available).

In addition, *criteria* for prescribing a time interval between subsequent routine (re)-calibration of the tester should also be considered necessary.

B–3). Professional tests providing confirmation of author's calibration procedure correctness
According to ISO 15197-2015 [5] in #6.3.3:
"Minimum system accuracy performance criteria" for trained operators:
a) 95 % of the measured glucose values shall fall within either ± 0.83 mmol/L (± 15 mg/dL) of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L

[c] Strictly speaking, the *standard reference material* is *pure* glucose, like, e.g., NIST (SRM) 917d D Glucose (Dextrose). However, a *control solution* is simply a certified *diluted glucose*, e.g. 140 mg/dL.
[d] Additionally, the *calibration of the strip batch* used with the tester should be taken into account: the middle value of the indicated range is the obvious "expected value", i.e. for that range the *nominal* value be 140 mg/dL. Therefore, also the offset (e.g. 143 mg/dL) *indicated on a strip box*, will contribute to incorrect tester readings—being also the nominal value of the latter 140 mg/dL for the range 100-125 mg/dL.

(<100 mg/dL), or within ± 15 % at glucose concentrations ≥ 5.55 mmol/L (≥100 mg/dL).

b) 99 % of individual glucose measurements shall fall within zones A and B of the Consensus Error Grid (CEG) for type 1 diabetes (see here in [8]).

Criterion A shall be applied to each reagent lot individually. The measured values from each lot shall be analysed and reported separately.

Criterion B shall be applied to the 3 reagent lots taken together, if necessary, and "All measured values from the 3 lots shall be combined before analysis and reporting."

The glucose reference values are defined in [9] as "the materials, reference measurement procedures, and reference measurement laboratories that are suitable for assigning glucose reference values".

The author made himself fasting tests (8-9 a.m.) by using the professional tester GIMA GDH-FAD.

The "full" apparatus provides i) a tester with instructions, ii) a control solution bottle (2 mL, deadline 2026-12-12, for *range (CTRL) 1* and *no* specified nominal concentration), iii) a box containing a few test strips (deadline for use 2026-12-13, with indicators for CTRL 0 (20-59 mg/dL), CTRL 1 (100–150 mg/dL) with no "desired value", and CTRL 2 (175–410 mg/dL)), and iv) a standard device for obtaining blood drops.

The test procedure requires first measuring the concentration of a drop of the control solution. If the measured value is within the indicated *range*, the apparatus is "valid" (*i.e. calibrated*; thus the subsequent measured value of a drop of blood will be valid).

Table 5 below shows the results for *both* Professional Tester GIMA, calibrated according to the manufacturer's Instructions and Tester Beurer2, calibrated according to author's procedure.

GIMA. The first test, with a GIMA strip on GIMA *control solution* range CTRL 1, provided a value of 121 mg/dL, below the *range central* value of 125 mg/dL—actually any special value is attributed by the GIMA procedure. Then, the GIMA strip was changed, and a drop of the author's blood was found providing the patient's glycaemia value 108 mg/dL, *valid* according to the GIMA procedure and well below the pre-diabetes range limit.

Beurer2. The author's procedure [1–4] was followed, using the current tester, Beurer GL50, with the corresponding strip from the Beurer current batch: the measured value was 134 mg/dL. It was then *corrected* according to the author's current calibration of that tester, made 2 days ahead with the Beurer control solution; the correction amounted to 1.021×0.869 = 0.887 mg/dL [e] and the patient's correct glycaemia value resulted to be 107 mg/dL 25% lower than the measured one and ≈ –1% lower than the GIMA measured one.

The professional GIMA procedure actually lacks some information that should also be available as needed to understand how it works: (a) the control solution nominal value, the "calibrated value", usually the centre of the range, is lacking, so is the way the value 119 mg/dL is obtained by the tester; (b) the GIMA strips are indicated to be valid on a range of ± 25 mg/dL centred on 125 mg/dL, but the *indication is lacking* whether the batch central-range value, 125 mg/dL, is valid or not (see FootNote e). In principle, the ≈ 1% higher professional value could be simply justified by the effect of an off-calibration of the trip-batch of 1.023, i.e. by a difference from 125 mg/dL of only 2.8 mg/dL.

Table 5: Professional test procedure applied to author's calibration and reading-correction procedure. Two testers were compared: Beurer2 and GIMA Professional. See the text for the procedure sequence followed to collect the data.

Last re-calibration	**0.887**					
Beurer2						
Reading (mg/dL)			**Test result (mg/dL)**	correction:	**mg/dL**	
119			**107**	25%	9 June	**Beurer2**
	0.908	*1.023*				
			108			**GIMA**
122			**108**	25%	10 June	**Beurer2**
	0.941	*1.061*				
			112			**GIMA**
118			**105**	25%	11 June	**Beurer2**
	0.884	*0.997*				
			107			**GIMA**
	0.91	*1,026*	**107**	mean	1.8	**Beurer2**
CONSISTENT		0.029	**109**	mean	2.6	s.d.

[e] if strip calibration = 1.021 is centred on 140 mg/dL and tester calibration = 0.869 is centred on 140 mg/dL.

3. Conclusions

The narrow range of pre-diabetes is very critical because it may determine the onset of full-blown disease if the measured values consistently exceed 125 mg/dL. It would require a higher quality of home or professional checks, which can be difficult to obtain according to the present instrumentation required by these tests. Therefore, proper re-calibration of test devices is crucial, although the author's decadal experience shows that it cannot be always ensured by current devices—unless the tester model is restricted to very specific ones, should any be available.

However, a procedure for such calibration has been proposed by the author [1–4], having now demonstrated its reliability in treating about a thousand tests performed overtime, as confirmed above in B-3).

Such a possibility is *totally lacking* so far in the presently versions of the Standard ISO 15197 [5], where a specific reference material is also lacking for the glucose solution needed to check testers. The admitted checks are only of the "pass/not-pass" type, without the possibility of tester recalibration to be used for *correction* of the measured values, as instead allowed by the procedure reported in [1–4].

Additionally, the terminology used in this field remains quite confusing and varies across the literature and the online information. A specific section or information template for terminology should be added to the standards, after ensuring that the glucose-level ranges are consistent with those defining the "absence", the "pre", and the "full" occurrence of the disease.

Moreover, it would be better, when necessary, the use of actual numerical values for glucose levels instead of just range nominal numbers (like e.g. "Range 3"), and to strictly prescribe the same from all manufacturers—currently a source of confusion for patients.

Should the calibration procedure not be found suitable to most patients' understanding or capabilities, it would be required to embed it into the software procedures of the testers, today, a minor problem.

The above conclusions do not apply to the current trend of avoiding the use of a blood drop for the tests, trying instead to take advantage of other human skin fluids: the problem of their use is accuracy, certainly much more difficult to comply with the needs of the pre-diabetes range.

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APPENDIX [Not Reported in the Paper Text]

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