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Short Communication

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A Case of Pre-Diabetes Showing Interesting Features when Monitored by Home Tests with Sound Measurement Science Tools

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Abstract

A study started immediately after the author having had a pancreas damage inducing a pre-diabetic disease, directed to check the quality of the results obtained by using the commercially instrumentation available for home-checking, taking advantage of the decennial experience of the author in primary measurement science (metrology), an interdisciplinary opportunity to get significant checks when correctly using the tools of such a discipline. The quality of the results, which are the ones daily obtained by millions of patients in the World, was showing some surprises and was far from satisfactory by using the prescribed method and the current instrumentation, with only some improvement in the past decade as to the quality of the latter, but not as far as the recommended measurement procedure is concerned.

Keywords: Prediabetes; Home tests; Test devices calibration; Test precision

Description

During one of his last trips abroad to attend a conference in Senegal in 2016, the author stayed in a modest hotel. One night, he decided to drink from a bottle of mineral water he found in the fridge. However, after a few sips, he suspected something was wrong and discovered that the bottle had already been opened and refilled with water that was almost certainly taken from the room basin. He had previously found the basin water to be of such poor quality that he decided not to use it even for cleansing himself. The day after, I got a body temperature reaching almost 39 °C. I got immediate medical aid from the Conference, and the doctor provided him an extremely strong antibiotics, allowing him to feel good enough to remain in Senegal for the next two days and then come back home to Italy on the booked airplane. At home, he had to take antibiotics for a full month to restore his health, except that it was diagnosed as damage to his pancreas, with a sharp increase in his glucose level (normally below 110 mg/dL) up to above 160 mg/dL. The immediate clinical checks brought him to a specific diet and to daily administration of metformin (Glucophage 1000) with home control of capillary blood, in addition to a few hospital checks of full blood. Since then, he made a systematic collection of home tests, amounting today to almost 2500 tests, supplemented by one hospital test per year, including glycated haemoglobin.

A first summary of his results was published in 2022 **[1]**, where it was reported that the first important feature, allowed by the professional capability of the author in measurement science, has a background of 55 years of primary metrology in the field of temperature measurements. The feature involved the actual precision of the tools used for home glucose testing: a strip for capillary blood sampling, then measured with a specific tester. Starting in March 2018, home testing was performed with the use of the commercial device sold by the same strip makers, and several brands were subsequently used **[2]**. The apparatuses were rarely found calibrated, even the off-the-shelf ones, and in the period 2018-2022, the off-calibration increased the value of capillary blood from more than +30% to a later average of 10-15% (**Figure 1**, from **[3]**). One general problem for this issue is that the pre-diabetes range is extremely narrow, from 101 mg/dL up to the no-disease top level of 125 mg/dL, above which the full disease is assumed to have started requiring the use of insulin to control the glucose level: the range width is of only ± 12 %, not ensuring the significance of the measured values when obtained with the precision of the home measuring apparatuses just indicated above. The precision of the commercial devices usually does not supply their accuracy level, except for a generic reference to the relevant International Standards, basically the BS EN ISO 15197:2015.

However, for a minimum of confidence in the measured values in pre-diabetes, at least about their reproducibility level, the devices should allow obtaining an accuracy of ± 5%. In that respect, the manufacturers also provide a so-called "control solution", having the task to allow the users to check the calibration of the testers, even at home (but also supposed suitable for professional use). There are several of these solutions, depending on the level that is to be measured in the blood. In this case, the level(s) considered here are: range 3 with a glucose concentration of 140 mg/dL, and range 4 with a glucose concentration of 280 mg/dL (see about the meaning of these ranges discussed in **[4,5]**, where only the first pertains to the pre-diabetic range—no accuracy indication is provided **[2]**—at a very high cost: 4 mL (=560 mg/L × 0.004 L= 2.24 mg of glucose @ ≈ $ 15, i.e. $3·750/L).

Here came, with some surprises, the results in **Figure 1**.

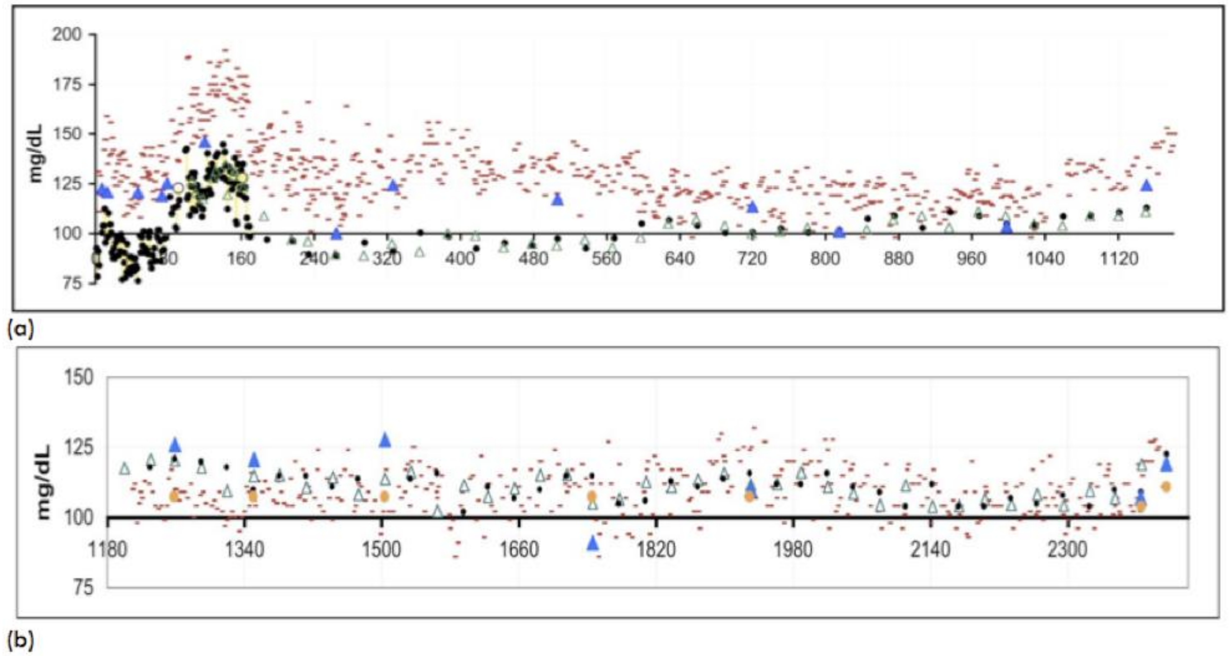

Figure 1: Database of marginal glycaemia measurements on whole capillary blood, performed on a singe patient: 6 different non-professional testers for home testing were subsequently used. On abscissa the progressive test days since 2009 (age 67); only since 2018 (Test Nº 450) the scale reports individual days up to June 2024 (age 82).

As to the off-shelf products, it was found that all 6 commercial testers did not show a correct calibration (offset from the nominal value δtester = 0), even by taking into account the fact that its calibration also needs using a single sensor “strip” for the correct range to be measured (for pre-glicaemia one is 100 mg/dL) from the current batch where a small drop of capillary blood is adsorbed. For the latter, the indicated value of the interval central value is taken as the “nominal”/correct one: a small off-calibration is often indicated—e.g., when the centre value is 103 mg/dL, an offset δstrip = 3% must be taken into account.

As to the results of the measurements, the corrected reading is thus: Rcorr = (δstrip × δtester) ·R, almost always found lower up to 30% for the older apparatuses (< ≈ 2020-22) used by the author. The tester corrections are also not stable in time, but tend to drift with time to higher values, so progressively increasing the incorrect glycaemia level readings. On the other hand, the reliability of the strip-batch calibration can only be established from the results obtained after use near half the total batch (i.e., after 8-12 of them over 25, the typical batch size) has been used: this fact can be observed, e.g., in **Figure 1**, where a few strip batches systematically are providing values higher by ≈ +10 mg/dL respect to a statistical mean value—a statistics can only be such if obtained by frequent home measurements, as performed by the author (≈ 2500 in 9 years, much more that done by normal people pre-diabetes sick). As an extreme case, occurred no more than for 10% of the batches, a specific analysis was necessary performed when already the first couple of strips indicated that the batch was out of specs by providing too high values **(Figure 1)**—no batch was found arising doubt to provide too low glycaemia value: this "favourable" condition was examined more carefully by comparing the results of two contemporary batches!

Regarding the comparison with professional measurements (e.g., in hospitals and clinics), a fundamental problem is the absence of stated measurement-uncertainty estimates on their certificates. In addition, such measurements are available only infrequently—typically only one or a few per year—providing too few data points to support any statistically meaningful analysis.. On the other hand, neither the few available professional results did normally come close enough to the corrected home testing values/trends. In case of pre-diabetes, only the measurement of glycated haemoglobin is the single professional test recommended at 4 times per year, so allowing to set the situation only on the long term—possibly never, if also considering that doctor's practice frequently consider the patient having under passed the pre-diabetes state and got full diabetes (thus needing insulin) after a level higher that 125 mg/dL has already been found twice over a period of time. As to the brands of testers/strips checked by the authors, they were they were presently 9 years over this study's total length, generally being in general only 1, max 2 per year available, because a new tester was bought only when the previous tester showed a tendency to drift away too fast, usually in a couple of years of frequent use. Finally, as to the method introduced by the author to always recalibrate frequently the tester by using the commercial control solutions (found stable within the validity period indicated), and exclusively using the corrected readings (and systematically repeating the measurement when in doubt), has been tested by the author [3] and found efficient and correct within an estimated accuracy within 5%.

The overall level of glycaemia since 2021, observed from the dispersion of the corrected data, was basically within a range of 105–120 mg/dL during the period of time when the Glucophage was daily assumed (from September 2016 to May 2025). Then the study has now moved to the effect of metformin, not of interest in this paper.

Conclusions

The study, started immediately after the author having had a pancreas damage inducing a pre-diabetic disease, has been directed to check the quality of the results obtained by using the commercially instrumentation available for home-checking, taking advantage of the decennial experience of the author in primary measurement science (metrology), an interdisciplinary opportunity to get significant checks when correctly using the tools of such a discipline. The quality of the results, which are the ones daily obtained by millions of patients in the World, was far from satisfactory by using the prescribed method and the current instrumentation, with only some improvement in the past decade as to the quality of the latter, but not as far as the recommended measurement procedure is concerned. The reproducibility is closer to 10% while a ≈ 5% is instead needed. The tester calibration is not stable in time, so it requires frequent recalibration, a duty that one cannot imagine being strictly/correctly performed by the large majority of the pre-diabetic patients (the diabetic ones already have such an invasive duty, a big difference), at best, typical only of professional activity and specific training. On the other hand, the latter is not performed for free, and in most cases, cannot, in all instances, provide a sufficient statistical “truth”, being based on too few results. That may be one reason why in recent times other “home test” methods are under development, e.g., using the so-called medical-clocks where the clock is equipped in such a way to perform an even continuous glycaemia test. Not being a medical doctor, the author cannot express an opinion in that respect, though he could in the future perform a similar study on them, if feasible.

However, they tend to avoid the use of (capillary) blood, but more experience is probably needed to understand the way to use other human body fluids/parameters for home measurement in a non-invasive way of the glycaemia level in blood. In the author's opinion, further improvement of the tester's precision and long-term stability is still necessary and urgent. Additionally, the reproducibility of the quality of the strip batches remains insufficient, at least to achieve a total accuracy of no more than 5%, which is needed for the pre-diabetic range. Home tests cannot be replaced solely by the glycated hemoglobin check, since diabetes can only be effectively managed with daily or weekly testing, even during its pre-diabetic stage involving millions of people—potentially allowing them to avoid developing the full disease, which is much more demanding. Finally, the instructions should include all important information, especially whether the indication is for plasma or capillary (full) blood, as there is an 11% difference in value that may be critical in such a narrow range. For a market worth billions of dollars, a reliable home test for prediabetes is already a critical need.

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