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Pre-diabetes Home Checks Revisited with The Tools of Measurement Science

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ABSTRACT

Diabetes is a chronic disease affecting a significant portion of the human population, namely those above a certain age. The condition often progresses from a stage known as "pre-diabetes" when the glucose concentration in blood before any fasting in the morning is above a conventional limit of 100 mg/dL. The engagement is much smaller in the phase of pre-diabetes than during the full disease, so that it must be carefully controlled, and normally drugs are needed to avoid stepping to the full disease. Consequently, regular tests of the glucose concentration are mandatory to confirm the "pre" (or better) condition. Frequent home tests are obviously a heavy burden for patients. In scientific terms, this means that statistics related to the concentration trend over time are useful and necessary: they are obtained by regularly using commercial "strips" and their testers, with instructions on how to handle them. The present study found unexpected drawbacks that make such tests unreliable, irrespective of the patient performing the measurements correctly.

Keywords

Prediabetes, Blood glucose, Home testing, Diabetes.

Introduction

Diabetes is a chronic disease affecting a large portion of the human population, namely those above a certain age. The condition often progresses from a stage known as "pre-diabetes" when the glucose concentration in blood before any fasting in the morning is above a conventional limit of 100 mg/dL. Only its evolution in time, causing that value to consistently increase above 125 mg/dL, is considered the full disease. This diagnosis often necessitates long-term management to prevent complications. While some patients may require insulin therapy, many are managed through oral medications and lifestyle adjustments. The engagement is much smaller in the phase of pre-diabetes, so it must be carefully controlled, and medications are sometimes introduced to prevent the progression to the full disease.

Consequently, regular testing of glucose levels is essential to confirm the "pre" condition (or better). Frequent tests, however, pose a significant burden for both patients and the healthcare system. Medical research has shown that focusing on a single parameter, which reflects the overall change in blood glucose over time, is the most effective approach: this parameter is currently the level of *glycated hemoglobin*. Measuring this level, which can only be done professionally through blood tests, is considered sufficient if performed at least once a year, and ideally once per trimester. The slow accumulation of causes leading to increased blood glucose is gradual enough to allow medical intervention and the prescription of appropriate medication.

However, the concentration of glucose in blood may also have a daily change, depending on food and on many other details of the everyday life of a patient, so the study of the short-term behaviour may also be considered important information for the best way to proceed with the therapy. In scientific terms, this means that also a statistics related to these trends is also useful or even needed. In this respect, in order to basically reduce the possibility of non

being informed of a slow increase in time of glucose concentration, the previous information may be too rare in time and should be paralleled by much more frequent tests, the home-tests—so-called because they are performed by the patients directly at home (with lower cost for them and no frequent involvement of medical structures).

Patients are not assumed to be scientists, and consequently, the equipment needed for the home tests is studied to be suitable for use by non-specialists and intended for simply performing a detailed procedure established by the specialists.

However, it has been found that the procedure specific for pre-diabetes is limited to what is necessary to limit the effect of the most common systematic errors in performing the tests: how to handle the supplied "strips" and their tester, having clean and dry hands, and making the tests before morning fasting. By following them correctly, the patient has only the task to record the obtained indications for communication to the medical doctors in order to get their judgment and provisions. Obviously, medicine is and remains the basic discipline to restore health, but in many cases, like in this one, prognosis does not only rely on medical competence. Typically, it also depends on the result of measurements: if provided by professionals in that field, they are normally trusted; when provided by the patient, much less so; by a medical doctor, sometimes not enough. The born doubt remains: if the measurement is assumed to be provided by means of a commercial measuring apparatus of a (trusted) company, how much is evaluated to be the competence of the patient in using it correctly? But also: is the quality of the commercial apparatuses sufficient?

In consequence, the author decided to make himself a long-term series of home tests since 2018: Figure 1 shows the last results obtained during the year 2025, while previous results can be found in [1].

Measurements need correct performance: the manufacturer's supplied information

Manufacturers only provide certified statistical parameters for their entire batch of measuring devices, such as strips and testers. However, a fundamental rule in measurement science is that each device must be calibrated, meaning its readings must statistically match the stated nominal value within acceptable quality standards.

The issue is obtained differently for the strips and for the tester.

Strips batch

In this case, the limit of the "expected" (i.e. valid) range of readings for the used batch is provided: e.g., a range 124–154 mg/dL with middle value 139 mg/dL denominated the "desired" (i.e. nominal)—i.e. its reference — value, corresponding, for "Range 3", to 140 mg/dL, the "nominal" *range value*. Any indication outside the above range is considered invalid; all other indications are expected to occur within that range for *the strips of that batch*—within the deadline of the period of use. If the mean value is stated to differ from the nominal Range 3 value, e.g., 139 mg/dL in that example, it means that the measured indication will reach 139 for a real value already being 140. In this case, any other measured value of a test on a drop of (capillary) blood with that strip batch must be corrected to supply the real value by a factor: (139/140 = 0.993) mg/dL. In fact, when the reference value of the strip is lower (139) than the nominal (real) one of the glucose nominal range (140), it means that all measured values are lower than the correct one, since 139 has to be measured when the real value is already 140. No way is available to check if the provided "desired" value is (correctly) valid.

Tester

The off-shell tester was first assumed by the author to be sold calibrated, but it was found that it was not always the case. Therefore, in all instances it must be considered by the patient to still has to be calibrated. In consequence, for the home re-calibration the manufacturer provides (by separate payment) a "reference mixture", in this case assumed to have a 140 mg/dL concentration of glucose—the mixture contains also other "passive" substances simply ensuring the stability of the glucose concentration in time during a full given period, typically 2 years, reported on the small (2.5 mL) bottle label.

Shaking the bottle before use is recommended by the author, even when not by the manufacturer, to ensure homogeneity of glucose in it: after shaking, one discards the first drop of solution on a clean paper tissue and then puts the second on the top of the bottle cover, clean and dry. The tester is then immediately used for the measurement, where a strip of the current batch has been inserted—for adsorbing some of the glucose mixture drop, until a value is displayed. If the value is different from the nominal concentration of the mixture (typically 140 mg/dL), all tester readings should be corrected accordingly: assuming the nominal mixture concentration is 140 mg/dL, if the reading was 155 mg/dL, a correction (140/155 = 0.903) mg/dL should be applied to get the calibrated value. The author has to notice that he normally found no information about the nominal concentration value, except a cryptic indication "Range 3", and no certified accuracy of that reference mixture value is provided—in both cases, so violating the rules set by the relevant International Standard for reference materials. In almost the totality of cases, the calibrated values were found to be lower and differing from the un-calibrated readings by up to 15%–20%. However, it is the *lack* of information about the glucose concentration value and precision of the supplied control solution that induces assuming exactly the nominal one of Range 3, i.e. 140 mg/dL, but a discrepancy is occurring in author's measurement.

By considering, e.g., the tests in Figure 1 after #600, the home-test indications (red symbols) have a mean value of ≈ (120 ± 9) mg/dL, while the home-test corrected values have a mean value of (105 ± 8) mg/dL, i.e. a correction of (15 ± 8) mg/dL, significant within the pre-diabetes range of 100-125 mg/dL (12% difference).

However, the patient also got two professional tests of glycate hemoglobin in times corresponding to tests ≈#650 and #840, getting values, respectively of 46 mmol/mol and 47 mmol/mol within the pre-diabetes range of 38-48 mmol/mol. Therefore, the home-test mean corrected values are at a safe 20% of the range, while the same amount of glycaemia from the (un-calibrated) indications is 95% almost at the upper limit of the range; instead the professional glycate hemoglobin values are at a mean of 85% of the glycate range, close to the upper limit. It is unknown to the author the accuracy of the professional measurements, but the fact that they do not report decimals in the values indicates that their uncertainty is supposed to be at best at the level of 1 mmol/mol, i.e. ±1/10 (10%)—thus a glycaemia level significantly closer to the upper pre-diabetes limit with respect to the corrected home tests and basically at the same level of the (uncalibrated) home indications. This would be an unresolved significant difference for the patient.

The setup is considered calibrated in the above way, with correction: (strip) × (tester) ones. Manufacturers do not indicate a deadline for the validity of the calibration of the testers. Instead, it was found normally the case to recalibrate the tester every month, i.e., after 10-20 tests—or when there is a change in the measured glucose value larger than 6-8%, and every time the batch of strips is changed, even if the new strip batch is indicating the same nominal value.

Such a procedure is not prescribed as the tester readings are considered accurate, at least as found by the author, which is instead *a basic fault presently affecting the market of home testing*, for about a dozen testers of different manufacturers.

Measurements need correct performance: the patient measurement expertise

Here comes the fact that correct measurements also require the patient to "at least understand and apply" the basic rules of "measurement science" correctly: it is a technical discipline valid for all types of measurements, becoming possibly science only when one is looking to the trusted accuracy of the results. So let us now examine what a patient needs to know for providing correct readings of his glucose level from those apparatuses, i.e., limiting our exploration to the technical aspects.

The re-calibration is a major drawback and difficult to resolve for the patients, normally non-specialists in measurements as most of the citizens are: in itself, the re-calibration procedure is not much different from the home-tests procedure on patient-blood, simply is not using the latter but a drop from reference mixture bottle—however buying such a bottle is no at all mandatorily required to the patients. From the author's experience, corrected values are found as much as ≈10-15% lower than the measured ones. The correct values can make for the patient a substantial difference between: (a) still being affected by pre-diabetes, requiring mild precautions; (b) already being affected by full diabetes, requiring insulin—a big change in the patient's full life, generally forever.

Metrological discipline is paralleled by a related discipline, providing the rules for the so-called "reference materials". They are standards for producing and then controlling the desired property of materials used to check the current production, by means of "certified" batches of those materials.

As already reported above, the home-testing procedure also needs to make use of such materials in order to check the correct calibration of the testers. All glucose-concentration mixtures sold by the same manufacturers of the test strips and testers are, in fact, reference materials, being that their use is assumed to have just the goal to check the calibration of the used apparatuses, i.e., ensuring that they are calibrated. Unfortunately, the kind of certification supplied is not found sufficient and even contrary to the International Standards: the nominal value and accuracy are not found supplied. As indicated in [2], it should be done. This study is also intended to supply suggestions in that regard.

Concluding remarks

The reported difficulties may represent a sufficient complication for decreasing the level of confidence in the home checks. To avoid that, the manufacturer could, in principle, include such a recalibration into the operation of the modern testers as an automatic procedure. Considering that a tester's life is normally safe only during 2-3 years (30-40 months), the tester could even be made to include an internal batch of strips and ≈1 mL of a (true) reference mixture, and then make the check procedure automatic with a modest increase in the cost of the apparatus.[1]

Given the importance of monitoring the glucose level for a very large fraction of humans above a certain age, including the author, he considered himself able to conduct a specific professional check, based on his own home checks, on the actual quality of popular home-testing procedures and commercially supplied instrumentation, of interest of patients and medical doctors.[2]

However, not being a medical doctor, the author cannot make a general statement about full validity of the reported comments and suggestions for other patients, but issues like ensuring correct calibration of the instrumentation looks important enough to report possible drawbacks in clinical examination of instrumental results.

[1] It might be quite more complicated in the future because today the goal is considered performing a continuous monitoring of glucose level avoiding the use of blood.

[2] He applied his long-term professional expertise in measurement science at the level of metrology regarding some Italian thermodynamic primary standards. [3] A specific duty of metrology is to determine the actual accuracy of the measurement processes in order to establish a level of confidence at the desired (or assumed *high*) level in other disciplines.

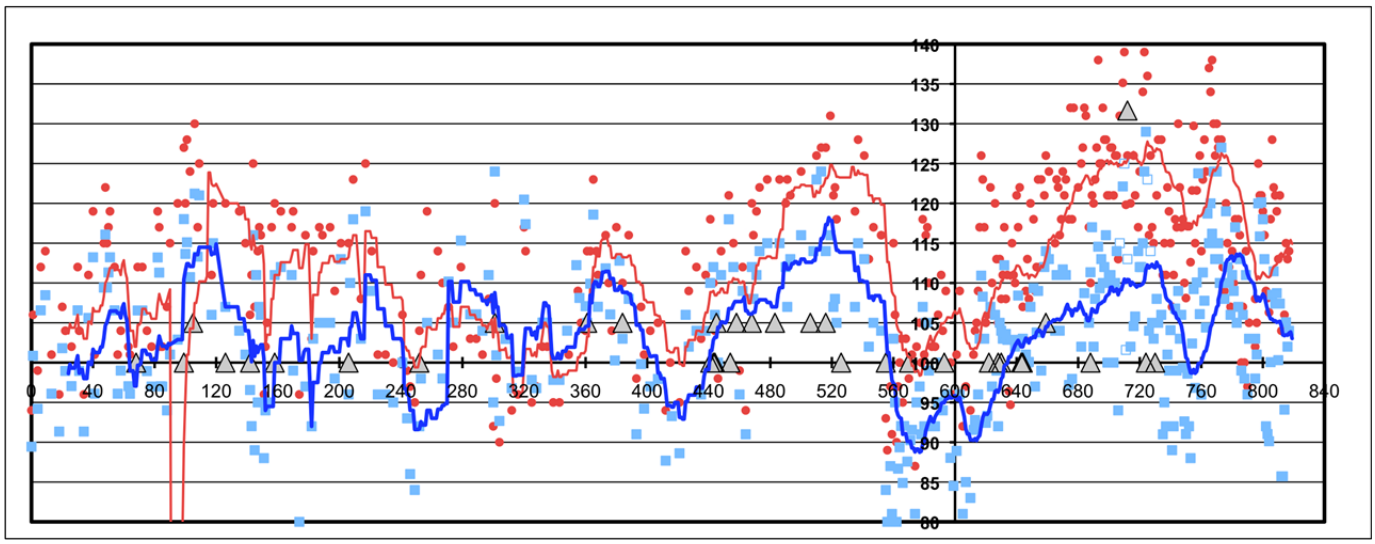

Figure 1: Latest example of home tests: from January 2025 to middle December 2025. Trend curves are for running mean of 25 data. Concentration is shown in mg/dL *vs* test #.

Red symbols and line: *uncalibrated*, (single drop at zero at #90: no test). Blue symbols and line: *calibrated*. Triangle, gray: @"100" *time* of strip-batch change (@"105" same for strip batches found with up to ≈10% higher-value indications).

Until *test #560* daily assumption of Glucophage: a periodic oscillation-like of glucose concentration is shown, also with some under-passing of the lower pre-diabetic level 101 mg/dL. From *test #560* preliminary checks of Mylan metformin assumption effect after short-period of *no*-metformin, repeated on 600. Again, periodical (corrected) concentration values shown also < 100 mg/dL—as low as ≈80 mg/dL. From test #610 until #730 *no-assumption* of metformin (nor other drugs) *at all*, then Mylan assumption until #760, then again suspended from #785, then again Mylan assumption.

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