The constant evolution of techniques has progressively modified the interactions between laboratory professionals, clinicians and patients, leading all of them to adapt their practices accordingly. A good example can be given with diabetes mellitus management. In this disease, patient education is a critical factor for the success of treatment. Patients have already been associated for decades to the daily evaluation of their glycaemic control either using urinary test strips or glucometers. Thus, they are used to participate in the production of biological data. However, the results obtained have been for long systematically verified at the laboratory level either by measurement of venous blood glucose or by the evaluation of other biomarkers like HbA1c. New tools and practices allow now patients to be directly involved in the actual production of their biological results. Their participation may occur from the preanalytical level by performing blood collection to the production of results which are directly used by the clinicians. Two examples may be found in this issue of Clinical Chemistry and Laboratory Medicine.

The first one refers to new practices in place for HbA1c evaluation. HbA1c is part of routine in clinical and laboratory practice for the follow-up of patients with diabetes mellitus. After decades of improvements, including the international standardization of methods, HbA1c values issued from most laboratories are now recognized for their reliability and constitute a strong basis for recommendations regarding screening, diagnosis and monitoring of diabetes mellitus [1, 2]. A majority of HbA1c measurements are performed in laboratories using dedicated devices (HPLC or capillary electrophoresis for example) or analytical platforms, but also in point-of-care testing settings, especially for outpatients during follow-up check-ups. According to the situations, samples used for HbA1c determination are made of venous whole blood or finger capillary blood and processed immediately without additional treatment.

These usual conditions of performance of HbA1c assays are satisfactory in most situations. However, in some circumstances, it is not possible to immediately perform HbA1c assay (for example because of the long distance between the collection place and laboratory facilities or, hopefully not frequently, in case of quarantine, as it recently happened during COVID-19 pandemic). In such cases, dried blood samples can be sent to the laboratory after deposition on a dedicated piece of filter paper. This type of procedure, which is commonly used for neonatal screening, may also be applied to HbA1c. However, when compared to standard laboratory procedures, conditions of sampling, storage and transportation to laboratories may constitute critical points for the reliability of results. In this regard, it is important to carefully evaluate the validity of pre-analytical conditions of such measurements in the real life, besides making sure that validated analytical methods are properly used in the laboratories with this specific matrix. Although an abundant literature is available on this topic, technical conditions are not always clearly detailed and evaluated in publications. Thus, uncertainties remain concerning the reliability and added value of these processes.

In this issue of Clinical Chemistry and Laboratory Medicine, a comprehensive review on remote HbA1c testing via microsampling has the merit to have exhaustively listed and systematically analyzed the technical conditions described in various studies devoted to this topic [3].

This manuscript underlines different important points. First, the collection of blood microsamples is a crucial step, but it seems to turn out from most studies that dried blood samples can be collected by a non-experienced phlebotomist or even by patients themselves without significant effect on the results, which is an important information in the view of actual patient involvement. This however implies to ensure a preliminary education of the patient by delivering clear explanations regarding sampling techniques, using different means like brochures or video messages. Second, conditions of transportation and storage are obviously very important for sample stability and thus HbA1c result. Indeed, the interval between blood collection and reception by the
laboratory may reach several days. However, literature conclusions are not very clear, necessitating to verify in each specific situation the influence of these conditions on the final result. Like in the case of whole blood stability, storage at −70 °C appears to be the preferred solution. Similarly, methods used for assaying HbA1c from dried blood spots seem to give satisfactory results, like in the case of whole blood assays. Third, the opinion of patient, which is a major point to consider, has been evaluated by questionnaires and proved to be very positive regarding these conditions of sampling.

Another example of direct interaction between the patient and his/her biological status is given in another manuscript of this issue, devoted to this evaluation of continuous glucose monitoring (CGM) benefit in patients with type 1 diabetes [4]. Times have gone since the only ways to evaluate glycaemic control were the assays of blood glucose at the laboratory after venipuncture. Even glucometers will probably be considered devices of the past in a near future. CGM systems, which are minimally invasive devices, allow a continuous measurement of interstitial glucose and provide immediate integrated information on the quality of glycaemic control, which can be forwarded to the clinician. They are much more acceptable for patients, especially children than repeated finger punctures, and thus meet with great success among both patients and clinicians.

Based on three significant clinical cases, the authors of this paper highlight the advantages of CGM over classical laboratory tests, especially in the case of presymptomatic type 1 diabetes, where it could be an earlier indicator of metabolic deterioration. Without disqualifying well established tests of diabetes monitoring like HbA1c, these observations demonstrate the added value of new approaches, which can contribute to reassess the place of the different ways of evaluation of glycaemic control according to the clinical situations. It is likely that besides HbA1c, CGM measurements will be more and more used in all type of patients with diabetes mellitus, not only type 1, whereas HbA1c should have a growing importance in diabetes diagnosis and screening.

Besides CGM performance in the assessment of diabetes control, the demonstration of the obvious improvement of quality of life by the use of CGM, avoiding regular finger punctures and providing automatically results which can be sent to the physicians by electronic way, must not hide the importance of using well characterized and calibrated assay methods. The working group established by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) on CGM has clearly explained the challenges related to the traceability of results obtained by CGM to higher order standards and/or methods. This group aims at defining a traceability chain for CGM systems as well as procedures and metrics for the assessment for their analytical performances [5]. Indeed, the fact that biological results are produced at the patient’s level does not rule out the active involvement of laboratory professionals and their scientific societies.

Together, these two papers give meaningful examples showing that patients may now be active participants in the management of their biological follow-up, including pre-analytical and/or analytical steps of testing, data collection and result interpretation. They underline the necessity to explore, besides classical laboratory processes, the possibility to put in patient’s hands a part of the production of their biological analyses. Indeed, patients are more and more informed and aware of progresses of medical and biological sciences and technologies, and wish to be actively involved in the management of their disease. These facts must be considered in a prospective view by physicians and laboratory specialists, in the global frame of societal evolutions leading to an increase of patient’s responsibility and involvement in public health.

This evolving situation also highlights the need for an optimal patient education in order to ensure the correct interpretation of results by the professionals. New strategies have to be established, in which laboratory medicine specialists must take an active part and fully exert their responsibilities, besides clinical management, playing a role outside their classical exercise in laboratories.

References