Effects of Analytical Goals on Evaluating Performance of HbA1c Measuring Method

R. MOHAMMADI (DCLS, PHD)
HbA1c test plays a critical role in management of diabetic patients
its measuring method must be acceptable
According to Diabetes Control and Complications Trial (DCCT), HbA1c results <7.0% show good glycemic control and results >8.0% show poor glycemic control. In order to properly classify an individual with an HbA1c value of 7.5%, the measurement error should not exceed ±0.5% (as absolute value of HbA1c), which equals relative total error of ±6.7%. Indeed, if the measurement error is greater, a patient of 7.5% would be indifferently classified in both good and poor glycemic control categories and this obviously would not be acceptable.
It is the **responsibility** of clinical laboratories to continuously monitor the performance of commercial methods in use, both by the implementation of a proper internal quality control (IQC) and participation in appropriately organized external quality assessment schemes (EQAS). Efficiency of both of IQC and EQA is strongly affected by selected analytical goals.
MATERIAL AND METHODS:

- During eighteenth and nineteenth runs of (EQAP), two freshly prepared commutable patient QC samples were sent to 650 and 858 laboratories which used five commonly used HbA1c kits.
- Target values for total group and also for peer groups were calculated.
Performance of each laboratory was determined according to two different allowable total errors (TEa), including ±6% and ±20%, which are suggested by National Glycohemoglobin Standardization Program (NGSP) and Reference Health Laboratory of Iran, respectively.
when we used TEa of ±20% for evaluating HbA1c method performance, about 11% and 9% of participant laboratories had unacceptable performance during EQAP-18 and EQAP-19, respectively.
But when this evaluation was performed according to TEa of ±6%, unacceptable results increased significantly to 50% and 55%, respectively.
Using improper analytical goals leads to misinterpretation of IQC and EQA results. Analytical goals must be defined in such a way that the test could save its clinical usefulness.
In order to maintain clinical usefulness of HbA1c results we need to reduce TEa of ±20% to ±6% and improve HbA1c measuring method performance.
In 2007, the CAP used wide acceptance limits of ±15% for evaluating performance of laboratories measuring HbA1c. In 2008, the CAP narrowed this limit to ±12%, and then in 2009 to ±10%, in 2010 to ±8%, in 2011 to ±7%, and finally in 2013 to ±6%.
As in United States, in which CAP plan to gradually tightenning of acceptance limits from ±15% in 2007 to ±6% in 2013, in Iran gradually thightenning of TEa from improper ±20% to proper ±6% is necessary. In this regards, Iranian clinical laboratories that have unacceptable results, must do corrective action to reduce their analytical errors or use another HbA1c measuring methods that has acceptable performance.