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Commentary

Recommendations for in-clinic PoCT for diabetes management in India

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ABSTRACT

A panel of expert diabetologist clinicians developed consensus standards to address the quality gaps inclinic point of care testing (PoCT) especially pertaining to diabetes care and management in India. The following summarized principles were established- 1. PoCT definition, 2. Advantages and critical aspects of PoCT including guideline recommendations and accreditations, analytical factors (pre &post analytical included) and consensus reached for an ideal PoC analyzer and 3. Key recommendations on in-clinic PoCT implementation by the panel. The experts suggested next steps that included key comparative (PoCT vs NGSP accredited lab) and patient benefit studies on PoCT.

1. Introduction

Point of care testing (PoCT) has recently become the topic of interest among clinicians in India especially pertaining to diabetes care. A fully automatic device designed to deliver clinical results on the spot for diagnosis, conveniently suffices a beneficial approach to both the clinician and the patient. PoCT in diabetes care has eventually evolved with the latest technologies, certified by renowned boards or associations making them eligible as reliable tools for the diagnosis and management of diabetes. To understand the relevance of in-clinic Point of Care Testing (HbA1C & other diabetes relevant tests) in India from an expert's point of view, an advisory board meeting was held under the aegis of Diacon conference 2016. The panel of experts in diabetes discussed their views and opinions from their clinical experiences on 'In-clinic PoCT for diabetes management'.

2. Objective

The objective of this advisory board meetingwas to collect all the necessary information from practicing clinicians in the area of diabetes, so as to arrive at an expert consensus document on the topic, "Recommendations for using in-clinic PoCT for diabetes management, with on the spot evidence-based decisions leading to better clinical outcomes and patient benefits."

The Experts contributed their recommendations on the advantages and critical aspects of using in-clinic PoCT HbA1c in diabetesmanagement and had a detailed discussion on the following key discussion points:

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- Standard definition of In-clinic PoCT for diabetes management
- Its advantages and critical aspects
- Application of in-clinic PoCT for diagnosis and/or monitoring
- Necessary approvals, certifications and legal registration for wider acceptance
- Requirement of an India Validation study/trial (method comparison with gold standard)at an National Glycohemoglobin Standardization Program (NGSP) accredited Lab
- Standard reporting format

3. Definition

The College of American Pathologists (CAP) defines "PoCT as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories" [1].

Whereas, the Food and Drug Administration (FDA) similarly defines PoCT HbA1c as a "device used to measure the percentage concentration of hemoglobin A1c in blood. Measurement of hemoglobin A1c is used as an aid in the diagnosis of diabetes mellitus and as an aid in the identification of patients at risk for developing diabetes mellitus" [2].

Automated PoCT devices are designed to allow for "real time" screening, diagnosis, and monitoring in diabetes care and can be used for thedetermination of glycated hemoglobinA1c (HbA1C), lipid profile, albumin, creatinine and albumin/creatinine ratio (ACR), C-reactive protein (CRP) and urinalysis dipsticks [3].

4. Advantages and critical aspects of point-of-care testing

HbA1c is the biomarker and the Gold standard method for the diagnosis of diabetes. International guidelines recommend keeping a track of HbA1c value every 3 months in patients that are off target and/or after a therapeutic change, and two annual measurements to be conducted in all patients. In addition, international guidelines have included HbA1c measurement among the methods for diagnosis. Therefore, using the point of care HbA1C testing can easily be relied on to monitor for prediabetes, Type I or Type II diabetes mellitus effectively [4,5].

4.1. Clinical advantages of in-clinic PoCT for diabetes management [6,7]

- Improved turnaround time (often <5 min) by shortening pre-analytical, analytical and post-analytical steps
- Reduced therapeutic turnaround time
- Improved monitoring of certain conditions where frequent testing is desirable for diabetes
- Improved convenience and access to service e.g. for elderly patients
- Smaller sample volumes (0.3–1 μL) which may be less invasive
- Availability of rapid results to facilitate patient management
- Ability to provide laboratory tests in remote locations or outside laboratory hours
- Economic benefits may also be realized because although some PoCT testing is moreexpensive than other traditional testing procedures, PoCT may offer economic benefits interms of reduced clinic visits, length of hospital stay and hospital admissions.

4.2. Critical aspects of in-clinic PoCT - diagnosis and/or monitoring

4.2.1. Guideline recommendations and accreditations

American Diabetes Association (ADA), states that diagnosis of diabetes should be carried out by devices that are NGSP certified. World Health Organization (WHO) also included stating that HbA1c can be used as a diagnostic test for diabetes provided stringent quality assurance tests are in place and assays are standardized to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement [8].

With regard to this many of the PoCT devices presently available in the market are certified by the NGSP criteria [total coefficient of variation (CV) 43.1% in SI units and 42.1% in Diabetes Control and Complications Trial (DCCT) units].Some PoCTs in addition also meet requirements of CAP GH5 b (2015). Proficiency testing survey hence fitting into the ADA recommendations of HbA1c measurement and have an intra laboratory coefficient of variation (CV) of <2% and an inter-laboratory CV of <3.5% [9].

These findings support equivalent quality assurance (EQA) measures identifying the robustness of the testing system. Hence with respect to these evidences, in clinic PoCT is very well designated in-clinic PoCT for diagnosis and monitoring of diabetes [9,10]. Added to it, accuracy and precision was found to be similar to high-performance liquid chromatography (HPLC) laboratory testing method with similar CV (2%, 3%, and 1%, respectively) [11].

4.2.2. Preanalytical and postanalytical factors

PoCT devices are manufactured with a number of control processes to minimize the probability of pre-analytical and post-analyticalerrorsand also to detect errors when they occur. Barcoded strips on the device ensure correct calibration. Internal quality control checks like optimal operating temperature and humidity range, acceptable Hb range, coagulation or hemolysis of sample are a few features bringing PoCT a step higher as a diagnostic tool. According to clinical literature occurrence of preanalytical and post-analytical errors were almost negligible with PoCT, as factors such as transportation, multiple user handling, order verification and delayed reporting were all eliminated, with only operator errors reported to be common [7].

4.2.3. Analytical factors

Ideal imprecision goals for HbA1c should be a CV of <2% for HbA1c reported in % units (or <3% in SI units, mmol/mol). However, there are acceptable limits for bias and imprecision which vary between organizations; the College of American Pathologists (CAP) criteria state that acceptable limits of bias are ±6%, while the IFCC Task Force on HbA1c Standardization recommended using a sigma metrics approach to evaluate analytical error. The NGSP recommends that for method certification 37 out of 40 HbA1c tests should be within ±6% relative to the standard reference laboratory measurement [12].

4.2.4. Consensus reached for an ideal PoC analyzer

- PoCTHbA1C should have an acceptable performance, standardized to the established reference, NGSP certified, simplified operation without the requirement of any costly instrumentation, and Clinical Laboratory Improvement Amendments (CLIA) waiver [13]. CLIA classifies tests according to complexity into waived and nonwaived categories [14].
- Should have a good memory to store on an average of 500 patient test samples and control samples results.
- Capability to share data with the Clinical management software that handles all patient data. Data could be collected or sharedin a simple manner e.g. via a USB, RS 232 port.
- Data on device operations should be easily retrievable. This data can be used to troubleshoot or to provide more information & insights on the clinical use of PoCT.
- Diabetes relevant parameters (HbA1C, lipid profile, blood glucose, albumin creatinine ratio, urine micro-albumin etc.) should be brought together on a single platform.

- HbA1c results should be reported in both NGSP (%) and IFCC (mmol/mol) units along with eAG (in either mmol/L or mg/dL), although the panel had a greater preference for NGSP (%) [15].
- 'No result is better than a wrong result'- In-clinic PoCT should give an information/error code and no result should be reported/displayed, when a correct result may not be possible to achieve due to factors such as improper use of the device, or sample contamination, inappropriate sample or anything else. Understanding the cause of information/error code can lead to its rectification.

5. Key recommendations [16,17]

- The PoCT environment should be clean and well-lit and may need temperature control. Service managers must perform a risk assessment of testing procedures. Equipment must be provided for the safe disposal of blood and contaminated consumables; staff must be trained in the use of this equipment.
- Internal quality control (IQC) and EQA programs may be established.
- Collection of specimens must be performed with accurate identification of the patient or client and ensuring traceability of the specimen to the report.
- PoCT must only be performed by operators who have undertaken training by a recognized training organization, course or program and have demonstrated that they are competent.
- Documentation must include the name of the operator, date, patient identity details, results, lot number of calibrant (if required), reagents and quality control materials. This must be recorded at the time of analysis. A record of any maintenance and repairs and should also be kept. It is advisable to keep an 'error log' to assist any investigation of potential incidents.
- Quality control procedures must be utilized to ensure that all testing is performed using instruments, reagents and consumables which are working correctly and according to specifications.
- PoCT technology should be fully automated to avoid errors and should have minimal manual intervention.
- Reagents and consumables must be stored in accordance with the manufacturer's recommendations.
- PoCT equipment should be uniform to allow simplification of training, storage and supply of reagents, servicing and maintenance.

6. Suggested next steps by the advisory board

- The panel agreed that further evaluations should be carried out to prove PoCT HbA1c as an eligible device to diagnose diabetes by conducting studies on the following topics:
- Clinical evaluation study on in-clinic PoCT HbA1c against NGSP accredited Laboratory in India
- Patients beneficial outcome with in-clinic PoCT HbA1c

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