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Consensus Guidelines

# Consensus guidelines for glycemic monitoring in type 1/type 2 & GDM

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ABSTRACT

Stringent monitoring of blood glucose in diabetes plays an important role as the treatment of the disease itself. Blood glucose monitoring (BGM) strategies such as measurement of Hb1Ac, Self-Monitoring of Blood Glucose (SMBG) and Continuous Glucose Monitoring (CGM) plays a vital role in achieving the important goal of preventing long term complications of diabetes. Although the use of BGM is recommended by various international guidelines in T1DM and T2DM, there is no consensus on the utility of BGM in India. So, there is a need to develop a guidance for uniform monitoring mechanism among the care givers taking into account the variations and challenges that are unique to Indian population. A committee was established that comprised of physicians, researchers and other healthcare professionals having expertise in diabetes treatment to oversee the formulation of guidelines on different monitoring and treatment aspects of diabetes. Extensive literature searches were conducted to identify and analyze the evidence available on BGM. An initial draft of BGM guidelines was presented to core members who discussed the subject matter and presented their opinion. This was then taken to wider expert audience to invite their comments that were incorporated in the initial draft. The first compilation was presented at a conference attended by nearly 200 experts. Again, their opinion was sought and the next version was prepared which was sent to core committee members for the final inputs. The Indian consensus guideline on BGM using Hb1Ac, SMBG and CGM as the primary tools was then finalized.



## 1. Introduction

Diabetes mellitus is a chronic illness that requires continuous medical care and ongoing patient education to prevent acute and chronic complications. International Diabetes Federation (IDF) estimated that the number of people with diabetes in India would increase to 101.2 million by 2030 [1]. According to Cost of Diabetes in India (CODI) study, the mean direct annual cost of outpatient care for diabetes patients in India was INR 4724/-. The study also found that cost was 18% less for patients without complications while it increased to approximately 50% of the average in those with three or more complications [2]. Thus diabetes imposes a staggering financial burden on the health care system due to its imminent complications and complex care.

Patient centered approach i.e., individual preferences, needs, and values, is vital to improve diabetes outcome. Optimal glycemic control delays the development and progression of micro/macro vascular complications. The disease can be successfully managed through a collaborative approach from the physician and team members, government organizations, family and the individual patient.

Blood glucose monitoring (BGM) predicts the day to day fluctuations and variations in blood glucose levels and helps to control hyperglycemia. It also helps to avoid acute complications such as hypoglycemia and prevents the occurrence and progression of long term complications of diabetes. Hence, BGM is a crucial component of diabetes care and enables patient to modify the lifestyle and choose the appropriate therapy. Three primary tools to measure BGM are Glycated hemoglobin (HbA1c) measurement, Self-monitoring of blood glucose (SMBG) or interstitial glucose, and Continuous glucose monitoring (CGM). Several evidences from epidemiological and interventional studies exist to support the association of BGM with relieving of symptoms, reduction in complications of disease and improving diabetes outcome. Strowig et al. showed a downward trend in glycosylated hemoglobin level in patients who increased the frequency of testing ($r = -0.54$, $P = 0.01$) [3]. Similarly a recent

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meta-analysis suggested that SMBG reduced A1 C by −0.25% at 6 months [4].

There is a clear need to evaluate the clinical, metabolic co-relation and cost–effectiveness of BGM due to increasing prevalence of diabetes in India and the significant morbidity/mortality and huge costs associated with it. Although the use of BGM is recommended by various international guidelines in Type 1 Diabetes Mellitus (T1DM) and Type 2 Diabetes Mellitus (T2DM), there is no analogous consensus on the utility of BGM in India. Limited Indian publications on this topic have highlighted the importance, but have restricted acceptability due to differences of opinion among researchers and practicing physicians. In order to determine the value of BGM in patient care accurately, it must be integrated into a treatment protocol algorithm and guidelines for patient education.

So a consensus meet was planned to identify the key relevant issues, benefits/limitations and controversial findings relating to the use of BGM based on the landmark, recent and other evidences. These guidelines intended to support the role and to propose clinical recommendations for practice and application of three BGM modalities viz., HbA1c, SMBG and CGM in management of diabetes.

## 2. Methodology

The development of diabetes guidelines followed a series of stages. The process started with the formation of a core committee comprising of health-care professionals/clinicians/researchers having wide expertise in treating diabetes across varied group of patients viz., pediatrics, youth, elderly and pregnant population. The committee members were chosen from different geographical areas of the country for better purview of the regional disparities prevailing amidst diabetes care. The core committee met, discussed and decided that five guidelines would be framed for diabetes management in India. A separate committee was formed for each of the guideline. Each guideline committee consisted of 6–7 members and one chairperson.

Experienced individuals with thorough knowledge of the subject were assigned to prepare the draft version of the guidelines. The guideline preparation started with extensive literature search from electronic databases, primarily MEDLINE, EMBASE, COCHRANE etc., and studies pertaining to the topics were identified. In general the recommendations are based on international and Indian evidences and guidelines, published over the last few years. Evidences included randomized or nonrandomized clinical trials, meta-analyses, evidence based reviews, case studies, cohort studies, epidemiological studies. Opinion of expert panel was also taken into account. The evidences were graded as shown below:

| Levels of evidence | Type of evidence |
|---|---|
| A | Randomized controlled trials or meta-analyses or systematic reviews |
| B | Non-randomized controlled trial or uncontrolled randomized clinical trial |
| C | Observational trials or evidence based reviews or case studies |
| D | Opinion of expert panel |

The initial draft was circulated among the core committee members. The members of core committee met to discuss the subject matter, to provide expert opinions based on their extensive experience and to review the evidences. The draft was made available at the DiabetesIndia website and comments from global, regional and interested experts were invited. All suggestions and opinion of the members were then incorporated into the draft guidelines.

The first compilations of guidelines for diabetes management in India were presented at a conference attended by almost 3000 physicians. Each guideline was discussed at length and the recommendations were obtained from the group. A second draft of each guideline was formulated taking into consideration of all recommendations and suggestions put forward in the conference. The second draft of the guideline was sent for further review to the core committee and the physicians for final inputs. The guidelines were then finalized and published.

## 3. Objectives of consensus meet

- To set standards in practice for carrying out BGM safely and effectively.
- To propose clinical recommendations for the HbA1c, SMBG and CGM practices (including procedures) in Indian context.
- To make the clinical staff aware of varied aspects of BGM, including frequency and timing of monitoring, risk of errors involved with testing procedure, obtaining reliable blood samples, training and conducting appropriate calibration checks on the devices before use.
- To provide guidance on diabetes self-management education and on-going diabetes support.

## 4. Modalities of monitoring

HbA1c, SMBG and CGM are the three modalities of BGM which have been discussed here. We have provided evidences from various clinical, observational and meta-analysis studies to support the role of these three tools in diabetes care consecutively. Perspectives from different guidelines are also taken into consideration. Furthermore procedural recommendations have been included for an effective clinical performance among different population of T1DM and T2DM patients (newly diagnosed diabetes, youth, pregnant, pediatrics).

## 5. Glycated hemoglobin (HbA1c)

HbA1c should be performed during initial assessment and then as part of continuing care. The availability of the A1C as a Point of Care (POC) testing has been reported in small studies, to result in increased intensification of therapy and improvement in glycemic control [5,6]. However, two recent systematic reviews and meta-analyses found no significant difference in A1C between POC and laboratory A1C usage [7,8].

## 6. Evidence for association of glycated hemoglobin and control of diabetic complications

Both epidemiological and intervention studies have shown a relationship between HbA1c and diabetes related complications. Lower levels of HbA1c have been associated with fewer complications. While the evidence is stronger for microvascular complications, this relationship is also evident for macrovascular complications. An increase in glycated hemoglobin level is associated with greater risks of diabetes related coronary heart disease and stroke.

### 6.1. Epidemiological studies

Reported epidemiological data from the UK Prospective Diabetes Study (UKPDS) showing a significant association between mean updated HbA1c and clinical complications in people with newly diagnosed diabetes followed over 10 years. Each 1% increase in HbA1c was associated with a 21% (95% CI 17–24%, $p < 0.0001$)