

# Adherence to ICMR Guidelines for the Management of Type 2 Diabetes Mellitus in a Tertiary Care Hospital

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## Abstract

**Background:** Adherence to type 2 diabetes mellitus (T2DM) guidelines helps achieve glycemic control and minimize complications. This study evaluated the adherence to the Indian Council of Medical Research (ICMR) guidelines for the management of T2DM.

**Methods:** In this cross-sectional observational study, 250 prescriptions of T2DM were collected to assess their adherence to ICMR guidelines.

**Results:** The mean HbA1c of the patients was 8.39%. Ideal fasting plasma glucose, postprandial plasma glucose, HbA1c, and blood pressure levels were achieved in 23.2%, 16.4%, 17.2%, and 46.4% of the prescriptions, respectively. Foot care, lifestyle modification, tobacco cessation, and HbA1c advice within the last 6 months were present in 8, 164, 7, and 104 prescriptions, respectively. Eye examination was advised in 44% of the prescriptions. When indicated, initiation or intensification of anti-diabetic drugs, aspirin, and anti-hypertensive drugs was done in 86.8%, 37.4%, and 98% of the prescriptions, respectively.

**Conclusion:** Adherence was low for glycemic control, foot care advice, initiation of aspirin, and anti-diabetic drugs according to BMI. Guidelines were frequently adhered to for blood pressure control, advice for lifestyle modifications, initiation or intensification of anti-diabetic and anti-hypertensive drugs. The study inferred the need for better adherence to ICMR guidelines, which could be achieved by their periodic revision in light of new research evidence.

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**Keywords:** Type 2 Diabetes Mellitus; Adherence; Guidelines; Prescribing Pattern; Prescription

## Introduction

Diabetes mellitus is globally one of the fastest-growing health emergencies of the twenty-first century. It is estimated that 422 million people are suffering from type 2 diabetes mellitus (T2DM) worldwide, and 1.5 million people die directly due to diabetes every year (1). T2DM is associated with several chronic progressive complications, such as coronary artery disease, peripheral vascular disease, stroke, retinopathy, and nephropathy (2). It is imperative to maintain a euglycemic state in diabetics

using appropriate anti-diabetic drugs to prevent these complications. In 2018, the Indian Council of Medical Research (ICMR), India, released the guidelines for the diagnosis and treatment of T2DM and its complications (3). These guidelines envisaged the appropriate management of T2DM patients in terms of foundations of care, required investigations, outcome targets, selection of anti-diabetic drugs and insulin, and management of the complications. Following ICMR guidelines is essential for the

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management of diabetes mellitus in the Indian population, as these guidelines are tailored to the health needs of the population of our country, integrating the latest evidence-based practices to enhance patient outcomes. In addition, several professional international organizations, including the International Diabetes Federation, American Diabetes Association, and Canadian guidelines, have also published evidence-based guidelines for the management of T2DM (4–6). It is advocated that healthcare professionals must follow these guidelines to achieve ideal glycemic control (7, 8), although non-adherence is reported worldwide, which may adversely impact the outcomes in patients with T2DM, leading to micro- and macrovascular complications (9–12). Strict adherence to guidelines is advocated in the Indian population, where the burden of poor glycemic control (76.6%) is particularly high (13). In view of this, the present study investigated the adherence of prescribers to ICMR guidelines for the treatment, achievement of targets, annual checkups, monitoring, and follow-ups in the management of T2DM patients.

## Methods

An observational cross-sectional study was conducted on 250 prescriptions of T2DM patients, collected randomly

from the inpatient and outpatient departments of Internal Medicine after approval by the Ethical Committee for Human Research of the institution (vide letter LHMC/ECHR/146). For random selection, all the T2DM patients in the inpatient and outpatient departments fulfilling the inclusion and exclusion criteria were asked to pick a slip of paper with “selected” and “non-selected” written on it. Prescriptions of the first 250 patients who picked “selected” were included in the study.

The inclusion criteria were the prescriptions of both new and old patients with T2DM aged between 18 years and 65 years. The patients already on medications for T2DM (old patients) were included only if they had all their prescription records from the last year. Prescriptions and medical records of the patients were manually reviewed for information on investigations, pharmacotherapy, and advice. The collected information was analyzed for adherence to ICMR guidelines for treating T2DM (3) (Table 1). Non-availability of any desired information in the prescription or medical record of the patient was considered non-compliant. Data were entered in a Microsoft Excel sheet and were analyzed by applying formulae in Excel itself. Data are presented as means and percentages.

Table 1. ICMR guideline criteria for assessing adherence to the treatment of T2DM

ICMR Criterion		Level of control		
		Ideal	Satisfactory	High
<b>1a</b>	<b>Achievement of Targets</b>			
	a) FPG (mg/dl)	80-110	111-125	>125
	b) PPPG (mg/dl)	120-140	140-180	>180
	c) HbA1c (%)	<7	7-8	>8
	d) BP (mmHg)	<130/80	<140/90	>140/90
	e) BMI (kg/m <sup>2</sup> )	20-23		
	f) Waist-hip ratio	Men <0.90		
		Women <0.85		
<b>1b</b>	<b>Target levels</b>			
	g) Total cholesterol (mg/dl)	<180		
	h) HDL (mg/dl)	>45		
	i) LDL (mg/dl)	<100		
	j) TG (mg/dl)	<150		
<b>2</b>	<b>Monitoring and follow-up</b>			
	a) HbA1c advised	Within the last 6 months		
	b) Tobacco cessation advised	Yes		
	c) Foot care advised	Yes		

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Table 1. Continued

<b>3</b>	<b>Annual Checkups</b>	
	a) Lipid profile advised	Yes
	b) Fundus examination advised	Yes
	c) Blood urea and creatinine levels	Yes
	d) Urine protein estimation advised	Yes
	e) ECG advised if age >40 years	Yes
<b>4</b>	<b>Treatment</b>	
	<u>a) Lifestyle modifications advised</u>	<u>Yes</u>
	<u>b) Treatment initiation according to BMI</u>	<u>Yes</u>
	<ul style="list-style-type: none"> <li>• <b>Non-Obese with T2DM:</b> Start with sulphonylurea/meglitinide or glitazones, and an additional agent like metformin is added if control is not achieved with the single agent in two to four weeks.</li> <li>• <b>Obese people with T2DM:</b> Start with metformin and additional agents added if control is not achieved in two to four weeks.</li> <li>• <b>Lean people with T2DM:</b> Start with Sulphonylureas/glitazones if BMI&lt;18.5kg/m<sup>2</sup>.</li> </ul>	
	<u>c) Treatment initiation or intensification of anti-diabetic agent done where indicated:</u>	<u>Yes</u>
	<ul style="list-style-type: none"> <li>• <b>Glycemic control not achieved after 2-4 weeks of treatment.</b></li> <li>• <b>Treatment initiated if diagnosed as T2DM.</b></li> </ul>	
	<u>d) Treatment initiation or intensification of anti-hypertensive agent done where indicated:</u>	<u>Yes</u>
	<ul style="list-style-type: none"> <li>• <b>If BP &gt;130/80mmHg on 2 occasions 1 week apart.</b></li> <li>• <b>Patient diagnosed with hypertension and having unsatisfactory BP.</b></li> </ul>	
	e) <u>Aspirin prescribed where indicated:</u>	<u>Yes</u>
	<ul style="list-style-type: none"> <li>• <b>T2DM with MI/angina/hypertension/ smoker/dyslipidemia.</b></li> </ul>	

T2DM: Type 2 Diabetes Mellitus, FPG: Fasting Plasma Glucose, PPPG: Post Prandial Plasma Glucose, HbA1c: Glycated Hemoglobin, BP: Blood Pressure, BMI: Body Mass Index, HDL: High Density Lipoprotein, LDL: Low Density Lipoprotein, TG: Triglyceride, MI: Myocardial Infarction

## Results

### *ICMR guideline criteria for the achievement of glycemic, blood pressure, and lipid control targets*

Information regarding the estimation of fasting plasma glucose (FPG) either at the initiation of treatment or after 2-4 weeks of initiation or change in treatment was available in 226 (90.4%) prescriptions. As documented in Table 2, FPG levels were ideal (i.e., <110 mg%) in only 23.2% of the prescriptions and satisfactory (i.e., 110-125 mg%) in

17.6% of the prescriptions. PPPG was estimated in 203 (81%) prescriptions and was unsatisfactory in 102 (40.8%) prescriptions. Estimation of HbA1c was advised in 104 (41.6%) prescriptions within the last 3-6 months. Values of blood pressure recording were documented in 89.2% of the prescriptions. Of the prescriptions, 46.4% had ideal (i.e., <130/80 mmHg) control and 16.4% had satisfactory (i.e., 130/80 to 140/90 mmHg) control (Table 2).

Table 2. Achievements of ICMR targets for glycemic control, blood pressure, and anthropometric parameters

Parameters	Achievement of targets				Total (N=250), N (%)
	Ideal	Satisfactory	Unsatisfactory	Not mentioned	
	N (%)	N (%)	N (%)	N (%)	
a) FPG	58 (23.2)	44 (17.6)	124 (49.6)	24 (9.6)	226 (90.4)
b) PPPG	41 (16.4)	60 (24.0)	102 (40.8)	47 (18.8)	203 (81.2)
c) HbA1c	43 (17.2)	11 (4.40)	50 (20.0)	146 (58.4)	104 (41.6)
d) BP	116 (46.4)	41 (16.4)	66 (26.4)	27 (10.8)	223 (89.2)
e) BMI	00 (00)	00 (00)	00 (00)	00 (00)	00 (00)
f) Waist-hip ratio	00 (00)	00 (00)	00 (00)	00 (00)	00 (00)

FPG: Fasting Plasma Glucose, PPPG: Post Prandial Plasma Glucose, HbA1c: Glycated Hemoglobin, BP: Blood Pressure, BMI: Body Mass Index

Estimation of total cholesterol levels was done in 121 patients (48.4%), and target levels of total cholesterol (<180 mg/dl) were achieved in 83 patients. Triglycerides, high-density lipoproteins,

and low-density lipoproteins levels were mentioned in 120, 104, and 30 prescriptions, respectively. Table 3 shows the details of the achievements of lipid targets as per ICMR guidelines.

Table 3. Achievement of lipid targets as per ICMR guidelines

Study Parameters	Achievement of targets N (%)		
	Yes	No	Not mentioned
Total Cholesterol	83 (33.2)	38 (15.2)	129 (51.6)
High-density lipoproteins	34 (13.6)	70 (28)	146 (58.4)
Low-density lipoproteins	19 (7.6)	11 (4.4)	220 (88)
Triglycerides	78 (31.2)	42 (16.8)	130 (52)

### ICMR criteria for monitoring and follow-ups

HbA1c estimation within the last 6 months was available in 104 prescriptions. Out of 35 patients who had a history of cigarette smoking, only seven were advised tobacco cessation. Foot care advice and examination were done in only eight patients who had a mention of a history of foot ulcer in their prescriptions.

ICMR-recommended annual checkups advice

In 66 prescriptions, all the recommended annual checkups, including ECG, and estimation of urine protein, lipid profile, blood urea, and blood creatinine were advised. ECG and urine protein estimation were advised in half of the prescriptions. Approximately three-quarters of the prescriptions had advice on lipid profile, blood urea, and blood creatinine estimation during the last 1 year. Only 110 (44%) prescriptions contained advice on fundus examination (Table 4).

Table 4. The ICMR guideline recommended annual checkups

Annual check-up Parameters	Annual checkup		
	Advised	Not advised	Not applicable
	N (%)	N (%)	N (%)
Eye examination	110 (44.0)	140 (56.0)	-
Lipid profile	185 (74.0)	65 (26.0)	-
Blood urea/creatinine	192 (76.8)	58 (23.2)	-
ECG*	128 (51.2)	116 (46.4)	6 (2.4)
Urine protein	133 (53.2)	117 (46.8)	-

\*ECG recommended if age >40 years. ECG: Electrocardiogram

### ICMR guidelines for treatment

a) Advice for lifestyle modifications

Lifestyle modification in the form of physical exercise

and dietary advice was recommended in 164 (65.6%) prescriptions.

b) Treatment initiation according to body mass index (BMI)

Body mass index (BMI) was not calculated for any of the

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patients; hence, the treatment for T2DM was not initiated according to the BMI of the patients.

### c) Initiation or intensification of treatment

Initiation or intensification of anti-diabetic treatment on the basis of the patient's glycemic control parameters was

required in 164 (65.6%) prescriptions. Of these, initiation or intensification of treatment was done in 142 (86.6%). Aspirin was indicated in 179 (71.6%) patients but was started only in 67 (37.4%) patients. Anti-hypertensive therapy was indicated in 163 patients and was initiated in almost all (98%) of the prescriptions (Table 5).

**Table 5. Description of treatment initiation or intensification, where indicated**

Parameters	Treatment initiation or intensification, N (%)		
	Yes	No	Not applicable
Anti-hyperglycemic started/ dose increased if indicated	142 (56.8)	22 (8.8)	86 (34.4)*
Aspirin started if indicated	67 (26.8)	112 (44.8)	71 (28.4)**
Anti-hypertensive started if indicated	160 (64)	03 (1.2)	87 (34.8)***

\*Not applicable means there was no indication to start another antihyperglycemic drug or to increase the dose of anti-hyperglycemic drug in these patients as per ICMR guidelines, \*\*Not applicable means aspirin was not indicated in these patients as per ICMR guidelines, \*\*\*Not applicable means the antihypertensive was not indicated as per ICMR guidelines

## Discussion

Adherence to evidence-based guidelines for the management of T2DM is a cornerstone in achieving ideal glycemic control, which ultimately may prevent diabetes-related complications (14).

In our study, adherence to ICMR guideline targets for FPG (23.2%), PPPG (16.4%), and HbA1c (17.2%) levels was low (Table 2). Similar low adherence to T2DM treatment guidelines with respect to achieving ideal FPG (28.8%) and PPPG (16.7%) levels has been reported from Turkey (15). On the other hand, the achievement of mean HbA1c in Germany (6.9%) (16) and Switzerland (7.7%) (17) was better than in our study (8.34%). In our study, the initiation or intensification of anti-diabetic agents (if indicated) was advised in 87% of the cases, which was better than that reported by Toth et al. (18). In their study, half (50.5%) of patients who had not achieved targeted glycemic control received only one oral anti-diabetic agent and 14.4% did not receive any therapy (18).

In our study, blood pressure was recorded in 89% of the prescriptions and was ideal (<130/80 mmHg) in more than half of these cases. Anti-hypertensive drugs were initiated in the majority (98%) of cases where indicated (Table 2). In other studies, recommended blood pressure targets were achieved in fewer (27.8% to 41.2%) patients (11, 19, 20) and even anti-hypertensive therapy was initiated in fewer (60% to 75%) patients than in our study (11, 18, 21). The prescribers of our institution were probably more aware and vigilant toward the monitoring of blood pressure to detect hypertension and initiation of antihypertensive agents. Despite the ICMR guideline recommendation for the initiation of low-dose aspirin in T2DM patients with co-existing myocardial infarction, angina, hypertension, dyslipidemia or age <70 years (3) to

prevent any cardiovascular event (22); the aspirin use was lower (37%) in our study prescriptions whereas Burgmann et al. documented its use in 75% of T2DM prescriptions (17). Aspirin is an inexpensive and safe medication to lower cardiovascular complications in high-risk patients with T2DM. Aspirin underuse reflects possible gaps in awareness among clinicians regarding the guideline recommendations or the fear of potential adverse effects.

Regarding the achievement of targets of lipid profile in this study, ideal TC, TG, and HDL levels were attained in 68.6%, 65%, and 32.7% of the prescriptions, respectively (Table 3). Oh et al. reported almost similar achievement of TC and TG target levels in the Korean population. However, in contrast to our study, they reported a higher proportion of patients who achieved target HDL levels (11). The reason for achieving lower HDL targets could be that Indians have lower mean serum HDL-C levels compared to the Western population (23).

Regarding the adherence to the criteria for monitoring and patient follow-ups, estimation of HbA1c within the last 6 months was advised in 41.6% of the prescriptions, whereas Perez et al. documented HbA1c estimation in more patients (52.3%) (19). In our study, follow-up and advice related to foot care and lifestyle modifications were recommended to eight (3.2%) and 164 (65.6%) patients, respectively, although ICMR guidelines recommend these advices for all T2DM patients. Other studies from developed countries reported foot care advice more frequently as one of the non-pharmacological management strategies (15, 19). Routine examination of the foot and foot care advice to T2DM patients can prevent diabetic foot, leading to permanent disability (24). Similarly, lifestyle modifications, including regular exercise and an appropriate diet, are valuable in the management of T2DM (4-6).

The adherence to annual checkups advice for estimation of lipid profile, blood creatinine, urine protein and ECG recording was present in fewer prescriptions than that reported earlier (15). In our study, eye examination was advised in 44% of the patients, which was almost similar (32.8-50%) to other studies (11, 15, 19). The probable reason for low adherence could be that the physicians forget to give timely annual checkup advice. The use of electronic hospital prescribing with automatic pop-up reminders for physicians may be a viable solution, although paper-based prescriptions are presently practiced in our institution. Automated electronic reminders to patients for annual checkups using mobile-based applications may be another possible solution.

Waist-hip ratio and BMI were not recorded in any of the patients; hence, adherence to achieve the target levels and initiation of pharmacotherapy according to the patient's BMI could not be commented upon. This could be due to heavy patient load and time constraints in documenting these bodily measurements (25). ICMR guidelines recommended the initiation of pharmacotherapy according to patients' BMI, whereas, in contrast to the ICMR guidelines, the consensus statement of the International Diabetes Federation, American Diabetes Association and several other guidelines recommended initiation of metformin in all patients irrespective of BMI (4-6).

Poor adherence to any treatment guidelines could be due to physicians' and patients' preferences for the treatment, constraints of finances, time and facilities, and attitudinal issues (26, 27). Cabana et al. revealed physician-related factors like lack of availability of a guideline or lack of familiarity with it if available (26). There could be disagreement among physicians to follow particular treatment guidelines, which may be due to limited research evidence(s) supporting the recommendation and lack of periodic updates (28). American Diabetes Association guidelines are updated every year in light of the latest evidence (29). However, the ICMR guidelines considered in the study were framed in 2018 and have not been updated since. Hence, it is important to revise the guidelines in light of new evidence, which may further enhance the confidence of physicians in the treatment guidelines. Increasing awareness of clinicians regarding the importance of adherence to evidence-based guidelines by conducting regular workshops will play a pivotal role in improving practices.

### Conflicts of Interest

The authors declare that there are no conflicts of interest.

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