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## Assessment of Gaps between Standard Diabetes Treatment Protocols Available in India and National List of Essential Medicines and WHO Essential Medicines - A Brief Report



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### ABSTRACT

**Introduction:** Diabetes mellitus is a syndrome of multiple aetiologies characterized by chronic hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism resulting from defects in insulin secretion, insulin action, or both. In recent eras, India has witnessed a rapidly increasing epidemic of diabetes. Main objectives of the study are to identify the treatment gaps that are present in the diabetes mellitus treatment protocols available in India. Comparison of treatment guidelines with National List of Essential Medicines, WHO Essential Medicines List, and Indian Public Health Standards for diabetes drugs to evaluate deficiencies in the drugs available at all levels of healthcare delivery system.

**Methods:** Through analysis of all standard diabetes treatment protocols available in India and comparison with National list of essential medicines, World Health Organisation Essential Medicines List, and Indian Public Health Standards for diabetes drugs. **Results:** All the guidelines have Metformin as the drug of choice and the dosage varies from 250 to 2000mg/day. NPCDCS guidelines are based on the BMI of a patient. IPHS has a set of drugs for diabetes treatment, these drugs are available at all levels of healthcare delivery systems (i.e.,<sup>1,2,3</sup>). **Conclusion:** Essential medicines are required to provide minimum services at all levels of healthcare delivery systems. More drugs are to be included in all levels of care according to guidelines given by ICMR, NPCDCS for better management and control of Diabetes. Standard treatment guidelines have to merge with the EML and IPHS standards to make availability of medicines at all healthcare delivery systems and also novel policies regarding the availability of drugs according to the guidelines must be implemented in order to meet the deficiencies.



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## INTRODUCTION

Non-Communicable diseases refer to those conditions which are chronic, evolve slowly, and are likely to continue progressively unless intervened. It is broadly accepted that the global burden and risk of non-communicable diseases constitutes a key challenge in the 21<sup>st</sup> century.

Diabetes mellitus is a syndrome characterized by chronic hyperglycemia resulting from defects either in insulin secretion or insulin action. Diabetes is often associated with long-term complications, involving major organs like kidneys, nerves, eyes, blood vessels, and heart. <sup>(1)</sup>

In recent eras, India has witnessed a rapidly increasing epidemic of diabetes. India tops second in the world in terms of people living with diabetes. According to the ICMR–INDIAB population-based cross-sectional study, the prevalence of diabetes in India was found to be 7.3% whereas prevalence in urban areas is twice as compared to rural areas and the prevalence of prediabetes is 10.3% (WHO criteria) or 24.7% (ADA criteria). Economically developed states show a greater prevalence of diabetes than low developed states in the country. In the urban areas, a high prevalence of diabetes is found in people with middle and high socioeconomic backgrounds than in people with low socioeconomic backgrounds. And conversely, a higher prevalence of diabetes is found in people with higher socioeconomic status in rural areas. The main risk factors for diabetes are gender, genetic predisposition, socioeconomic status (high or low) age, obesity, hypertension in urban and rural settings. <sup>(2)</sup>

The current study mainly focuses on the comparison of various standard diabetes treatment protocols available in India with the National List of Essential Medicines (NLEM) and WHO Essential Medicines List available at all levels of healthcare delivery and the identifying gaps present in standard treatment patterns and NLEM, WHO essential medicines list and with Indian Public Health Standards for Diabetes drugs. This will help policymakers and government authorities to alert regarding the gaps and can help create new policies regarding DM management.

## MATERIALS AND METHODS

### VARIOUS TREATMENT GUIDELINES FOR THE TREATMENT OF DIABETES MELLITUS IN INDIA:

There are currently 3 guidelines available for the treatment of Diabetes Mellitus and the guidelines include,

1. ICMR (Indian Council of Medical Research) guidelines.
2. NPCDCS (National Program for the Prevention and Control of Diabetes, Cardiovascular diseases and Stroke) guidelines.
3. ADA (American Diabetes Association) guidelines.

Analysis of all the following treatment guidelines is compared with the National List of Essential Medicines (NLEM), WHO Essential Medicines List, and Indian Public Health Standards (IPHS) for Diabetes drugs to identify potential gaps that are present in treatment patterns and availability of drugs at all levels of healthcare delivery system.

## RESULTS

**According to ICMR guidelines treatment of Diabetes:** includes 1<sup>st</sup> line drug as Metformin, 2<sup>nd</sup> line drugs are the combination of Metformin with other OHA's that include, the 1<sup>st</sup> choice as – Metformin with Sulfonyl Ureas and Metformin with DPP4 inhibitors and Metformin with SGLT2 inhibitors. 2<sup>nd</sup> choice as Metformin combination with Alpha Glucosidase Inhibitors (AGI) and Glinides, Thiazolidinediones (TZD), and Glucagon-like peptide 1 receptor agonist (GLP1 RA). 3<sup>rd</sup> line includes triple therapy i.e., Insulin + triple oral R<sub>x</sub> (Table-1).<sup>(1)</sup>

### **According to ADA guidelines:**

It includes the 1<sup>st</sup> line drug Metformin. However, in the 2<sup>nd</sup> line drugs like Sulfonylureas, DPP4 inhibitors, SGLT2 inhibitors, Alpha-glucosidase Inhibitors are included. It has only one drug combination i.e., Metformin + Vildagliptin. Triple therapy includes GLP-1 RA with insulin (Table-1).<sup>(3)</sup>

**According to NPCDCS guidelines:**

The guidelines provide the treatment based on the BMI of individuals and the drug of choice as Metformin and sulfonyl Ureas (Glibenclamide -2.5to20mg). Triple therapy will be used if the glycaemic control is not achieved i.e., Insulin + OHA's (Table-1).<sup>(4)</sup>

**Table-1: Comparison of ICMR, ADA & NPCDCS guidelines**

ICMR GUIDELINES	ADA guidelines for Diabetes treatment	NPCDCDS GUIDELINES
1ST LINE DRUGS	1st line	<b>DRUGS</b>
Metformin	Metformin	Metformin
2nd line drugs along with Metformin	2nd line (Other options if Metformin is not tolerated)	Sulfonyl Ureas(Glibenclamide)
1st Choice	Sulfonylureas, Dipeptidyl peptidase 4 inhibitor (DPP-4i), Sodium-Glucose linked transporter 2 inhibitor (SGLT2i), or Alpha-glucosidase inhibitors.	Non-obese people with type 2 diabetes
Metformin + Sulfonyl Ureas	Combination Therapy	Sulphonylureas/meglitinide or glitazones.
Metformin+DPP4 Inhibitors	Metformin+Vildagliptin	Metformin
Metformin + SGLT-2 Inhibitors	Triple Therapy	Insulin
2nd Choice	Start the third agent from a class other than the two i.e., Glucagon-like peptide 1 receptor agonist (GLP1 RA)or Insulin.	Obese people with type 2 diabetes

Metformin+AGI	Metformin.
Metformin+Glinides	Sulphonylureas/ meglitinides or glitazones and/ or insulin
Metformin+TZD	Lean people with type 2 diabetes
Metformin+GLP-1 RA	Sulphonylureas and glitazones
3rd Line drugs along with Insulin + triple oral Rx	Insulin & Combination of oral drugs with insulin

DPP4: Dipeptidyl-peptidase 4, SGLT- sodium-glucose linked transporter, AGI-Alpha Glucosidase Inhibitor, TZD- Thiazolidinediones, GLP-1 RA- Glucagon-like peptide 1 Receptor Antagonists.

#### ESSENTIAL MEDICINES LIST FOR DIABETES MELLITUS MANAGEMENT:

**WHO ESSENTIAL MEDICINES LIST:** Drugs for diabetes in WHO Essential Medicines List (table-2), in OHA it only has Gliclazide and Metformin. In the insulin category – intermediate acting and Short-acting insulin are included. Glucagon is included for the treatment of hypoglycemia. <sup>(5)</sup>

**National List of Essential Medicines (NLEM):** In table-3 all Oral Hypoglycaemic Agents and Insulin are present in all levels of health care delivery systems i.e., 1<sup>0</sup>, 2<sup>0</sup>, 3<sup>0</sup> but glucagon is only present in 3<sup>0</sup> level care. <sup>(6)</sup>

**IPH Standards for Anti Diabetic Drugs:** In Indian Public Health Standards for diabetes management (table-2) include OHAs such as T. Biguanide and Chlorpropamide, Tolbutamide, Glibenclamide. The insulin category includes Lente insulin, Rapid insulin, Cry insulin, and Mixtard. These drugs are included in the IPHS for diabetes management. <sup>(7)</sup>

Table-2: Comparison WHO EML & IPHS Standard Drugs

WHO EML (Essential Medicines List)		IPHS Anti Diabetic drugs
<i>Insulin and other medicines used for diabetes</i>		Tab. Biguanide
<b>Drugs</b>	<b>Dose</b>	Tab. Chlorpropamide 100 mg
<b>Gliclazide</b>	Oral solid dosage form: (controlled release tablets) 30 mg; 60 mg; 80 mg.	Tab. Tolbutamide 500 mg
<b>glibenclamide not suitable above 60 years</b>		Tab. Glibenclamide
		Insulin Lente Basal
<b>Glucagon</b>	Injection: 1 mg/ml.	Inj. Insulin Rapid
<b>Insulin injection (soluble)</b>	Injection: 40 IU/ml in 10-ml vial; 100 IU/ml in a 10-ml vial.	Inj. Cry Insulin
<b>Intermediate-acting insulin</b>	Injection: 40 IU/ml in 10-ml vial; 100 IU/ml in a 10-ml vial (as compound insulin zinc suspension or isophane insulin)	
<b>Metformin</b>	Tablet: 500 mg (hydrochloride)	

Table-3: National List of Essential Medicines

<b>NLEM - Medicines used in Diabetes mellitus</b>			
<b>Insulin and other Antidiabetic agents</b>			
<b>Medicines</b>	<b>Category</b>	<b>Route of Administration/ Dosage Form</b>	<b>Strengths</b>
<b>Glibenclamide</b>	P,S,T	Tablets	2.5 mg, 5mg
<b>Insulin Injection (Soluble)</b>	P,S,T	Injection	40 IU / ml
<b>Intermediate Acting (Lente/NPH Insulin)</b>	P,S,T	Injection	40 IU / ml
<b>Metformin</b>	P,S,T	Tablets	500mg
<b>Premix Insulin 30:70 injection</b>	P,S,T	Injection	40 IU / ml
<b>Medicines used to treat hypoglycemia</b>			
<b>Glucagon</b>	T	Injection	1mg/ml

Note: P; Primary healthcare, S: Secondary healthcare, T: Tertiary healthcare

## DISCUSSION

### *Comparison of standard treatment guidelines:*

All the guidelines have Metformin as the drug of choice and the dosage may vary from 250 to 2000mg/day accordingly. In ICMR guidelines 2<sup>nd</sup> line drugs have Metformin in combination along with other OHA's. ADA guidelines state otherwise if the patient has tolerance to Metformin. Although, NPCDCS guidelines have no 2<sup>nd</sup> line therapy and it has a treatment regimen according to the BMI i.e., non-obese people with type 2 diabetes, obese people with type 2 diabetes, lean people with type 2 diabetes. NPCDCS guidelines have been followed by the medical officer as the treatment regimen depends on the BMI or obesity based on which drug of choice will be selected. Triple therapies in all guidelines include insulin and there is no description on which type of insulin is used in all guidelines.

***Comparison of IPHS with WHO EML and NLEM:***

If we compare IPHS with WHO EML and NLEM, it has more drugs in Sulfonylureas and more Insulin types.

In a comparison of the essential medicine list and IPHS standards, the list of Antidiabetic drugs is similar. Though the standard guidelines for treatment include DPP4 inhibitors, AGI's, SGLT2 inhibitors, TZD, Glinides-Meglitinides which are not listed in the essential medicines list or IPHS. In insulin, only rapid-acting and intermediate-acting insulin are present at all levels of healthcare according to NLEM India whereas, Glucagon is not included in IPHS standards. More drugs can be included in all levels of care according to guidelines given by ICMR, NPCDCS for better management and control of Diabetes. The prevalence of diabetes in rural and urban India in 1972 was 2.4% to 3.3% and respectively in the year 2019 the prevalence is 15% and 19% when compared. <sup>(8)</sup> There is a sharp increase in the prevalence, and the treatment guidelines have to adapt to the novel guidelines along with the availability of novel drugs in all levels of healthcare systems are necessary.

**CONCLUSION**

Essential medicines are required to provide minimum services at all levels of healthcare delivery systems. IPHS has a set of drugs for diabetes treatment, these drugs are present at all levels of healthcare delivery systems (i.e., 1<sup>0</sup>, 2<sup>0</sup>, 3<sup>0</sup>). And the treatment guidelines have the same drugs as the IPHS standards. But more drugs are to be included in all levels of care according to guidelines given by ICMR, NPCDCS for better management and control of Diabetes. Standard treatment guidelines have to merge with the EML and IPHS standards to make availability of medicines at all healthcare delivery systems and also novel policies regarding the availability of drugs according to the guidelines must be implemented to meet the deficiencies.

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