



Protocol for Management of Type 2 Diabetes Mellitus



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Acronyms and Abbreviations

DD	digital doctor
DHF	Dvara Health Finance
DM	diabetes mellitus
FBS	fasting blood sugar
HW	health worker
RBS	random blood sugar
PEN	Package of Essential Noncommunicable disease interventions for primary healthcare guidelines
SOP	standard operating procedures
STP	straight through process
T2DM	type 2 diabetes mellitus
WHO	World Health Organisation

Glossary

Digital doctor	Locally registered, remotely working doctor with legal authority to prescribe medication
Health worker	Locally recruited and trained health worker with minimum qualification of high school
Hypoglycemic	Defined as a condition with low blood glucose levels characterised by RBS<70 mg/dL
Type 2 diabetes mellitus	Most common type of diabetes, commonly associated with overweight and obesity.

Introduction and Background

Diabetes mellitus (DM), commonly referred to as diabetes, is a metabolic disorder characterized by high blood glucose levels.¹ Type 2 diabetes mellitus (T2DM) is the most common type of DM. It is most frequently seen in obese individuals, individuals with increased abdominal fat, and in Indians, even in thinner individuals.¹ T2DM is estimated to affect almost 70 million Indians by 2025, making it a major public health concern.² Unfortunately, a vast majority are still undiagnosed.^{2,3} Of those diagnosed, less than a third had adequate glycemic control.⁴ If untreated and not under control, diabetes can lead to serious damage to the eyes (retinopathy), kidneys (nephropathy), and nerves (neuropathy). Diabetes also increases the risk of cardiovascular, peripheral arterial, and cerebrovascular diseases.¹

Objective of Dvara Health Finance's (DHF's) NEEM Program

The NEEM program aims to improve health outcomes for its users while providing them with financing options for health events.

Annexures 1 and 2 describe the care model and human resource strategy.

Process Flow for Type 2 Diabetes Mellitus (T2DM) Management

i. Enrolment^a

The health worker (HW) engages with prospective NEEM subscribers, henceforth referred to as subscriber, to create awareness, discuss health issues, introduce NEEM program and its benefits, and onboard them to the NEEM program. This includes obtaining consent, scheduling a screening visit, and collecting the initial subscription fee.

ii. Assessment – Case History and Screening

1. The HW follows the screening protocol and enters relevant data in the NEEM360 platform.
2. HW measures glucose levels from capillary blood sample by following the below guidelines:⁵
 - a. HW preparation: Wash and dry your hands. Wear gloves and do not touch anything apart from the testing instruments.
 - b. Ask subscriber to wash hands and relax.
 - c. Apply spirit to a sterile cotton swab and wipe the fingertip that will be used for the test. Let the surface of the fingertip air dry. Place cotton on a clean surface.
 - d. Place a test strip into the glucometer.
 - e. Prick the side of the fingertip with the lancet to produce a drop of blood. Discard lancet in sharps box.

^a For further information regarding the process, refer to the NEEM Enrolment Training Document [link tbd]

- f. Hold the edge of the test strip to the drop of blood and wait for a few seconds until the glucometer shows a reading.
- g. Place the cotton swab on the pricked surface and let the subscriber hold it until bleeding stops.
- h. Discard cotton swab and gloves in the trash bag.
- i. Record accurate readings displayed on the glucometer without rounding them.
- j. Diagnosis of T2DM is established when there are two discrete random blood sugar (RBS) readings ≥ 200 mg/dL within 100 days; or fasting blood sugar (FBS) levels are ≥ 126 mg/dL.⁶

Notes on glucometer:

- The NEEM program currently uses Accu-Chek® Active blood glucometer, which meets ISO 15197:2013 standards.
- Perform weekly calibration of the monitor and each new pack of test strips together.⁵
- Disinfect it as recommended by the manufacturers.⁵

Note on blood glucose tests: If HbA1c test results from the past 3 months are available, HbA1c results will take precedence over FBS and RBS results, in that order.

iii. Diagnoses and Management

On assessing medical history and screening for T2DM, the subscriber would be categorized into:

1. [Non-T2DM case](#)
2. T2DM: Straight through process (STP), henceforth referred to as [STP-T2DM case](#)
3. [T2DM: Referral case](#)

An overview of the management is depicted in [Figure 1: Management of type 2 diabetes mellitus in registered users of NEEM program](#). The categories and respective management are described further below in the document.

1. Non-T2DM case

- If RBS is between 140 and 200 mg/dL: Lifestyle counselling on healthy diet, physical activity of 30 minutes/day, the harms of tobacco use, and harmful use of alcohol.
- If RBS < 70 mg/dL: Go to [Annexure 3](#) and check management of hypoglycemic condition.

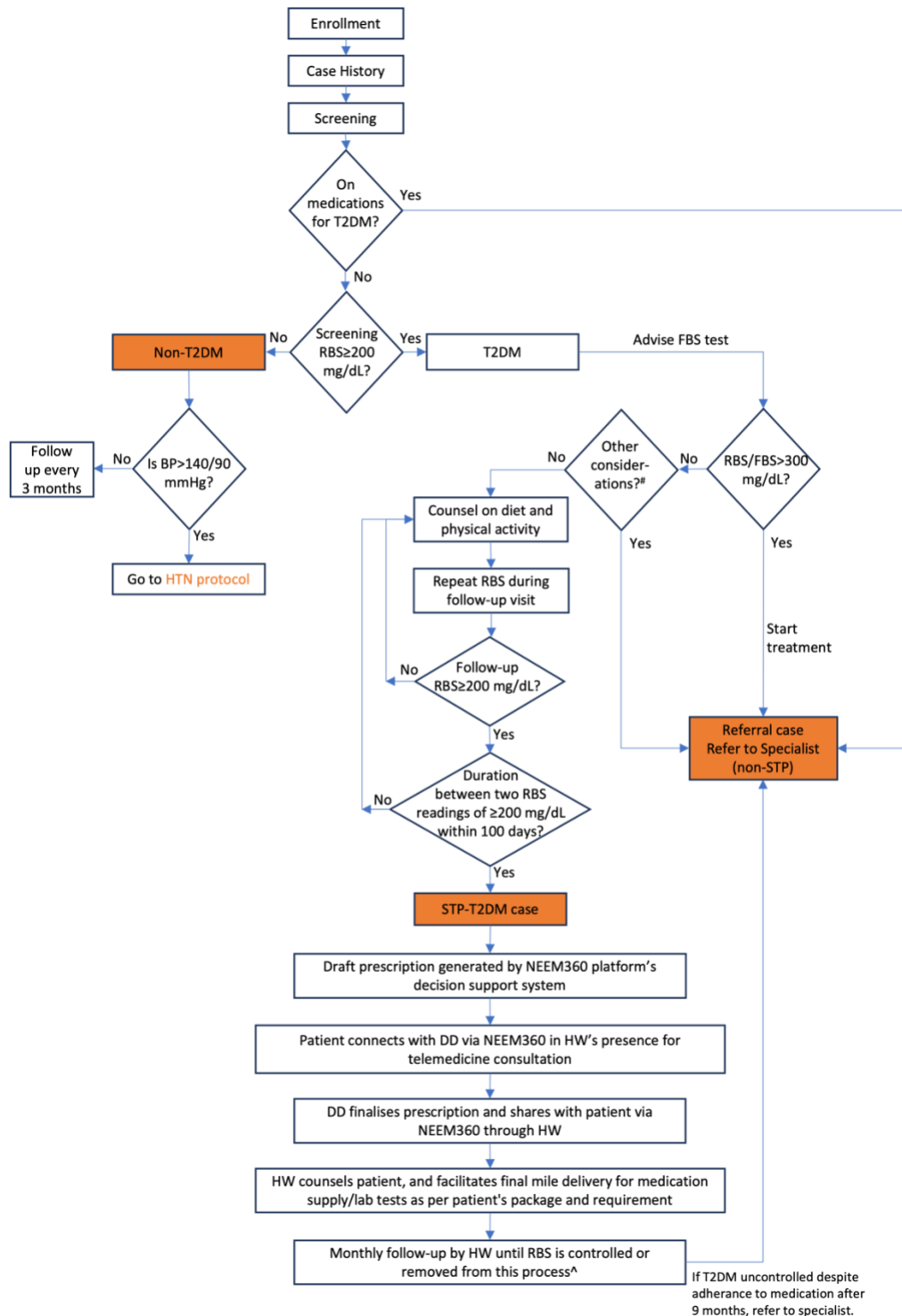


Figure 1: Management of type 2 diabetes mellitus in registered users of NEEM program

BP, blood pressure; DD, digital doctor; FBS, fasting blood sugar; HW, health worker; HTN, hypertension; RBS, random blood sugar; STP, straight-through process; T2DM, type 2 diabetes mellitus.

Currently pregnant; Is on dialysis; Gastro-intestinal side effects of Metformin are observed; Glycemic control is not observed despite adherence to STP-T2DM treatment for 9 months

^Migration/death/discontinued subscription etc.

2. STP-T2DM case

2.1 Eligibility

- Any two RBS readings between 200 to 300 mg/dL observed within a gap of no longer than 100 days
- or
- FBS between 126 to 300 mg/dL (during screening or follow-up visits)
- and
- Not on medications for T2DM
- Not currently pregnant
- Not on dialysis

2.2 Treatment

- Advise FBS test.
- Initiate pharmacological and non-pharmacological treatment. *Figure 2*: Treatment protocol of T2DM (adapted from WHO's Package of Essential Noncommunicable [PEN] disease interventions for primary healthcare guidelines 2013) demonstrates the treatment flow, which is derived and adapted from WHO's Package of Essential Noncommunicable (PEN) disease interventions for primary healthcare guidelines.⁶
 - NEEM360 platform's decision support system aids the Digital Doctor (DD) in diagnosis and generates an automatic draft prescription after the HW completes screening for STP patients. Patient connects with a DD via NEEM360 platform in HW's presence for a telemedicine consultation.^b
 - DD finalises prescription and shares it with patient via the NEEM360 platform through HW. Turn-around time between screening and sharing prescriptions with patient should not be greater than 48 hours.
 - In case DD rejects prescription, case is marked as non-STP and DD documents reason(s) for the rejection on NEEM360.
 - HW counsels patient on healthy diet and physical activity of 30 minutes/day.
 - HW facilitates the final mile delivery for medication supply/lab tests as per the patient's package, and requirement(s).
 - Follow-up at least once every 3 months by HW until RBS<200 mg/dL or moved to non-STP or removed from this process (migration/death/discontinued subscription).
- Escalate:
 - If gastrointestinal side effects of Metformin are observed, mark case as non-STP. Go to section [3. T2DM Referral case](#).

^b Refer to telemedicine consultations SOP here.

- If on medications or currently pregnant, or on dialysis, mark case as non-STP. Go to section 3. [T2DM Referral case](#).
- If improved glycemic control is not observed despite adherence to STP-T2DM treatment for 3 months after Step 2 in [Figure 2](#): Treatment protocol of T2DM (adapted from WHO’s Package of Essential Noncommunicable [PEN] disease interventions for primary healthcare guidelines 2013), mark case as non-STP. Go to section 3. [T2DM Referral case](#).
- If RBS or FBS >300 mg/dL, mark case as non-STP. Go to section 3. [T2DM Referral case](#).

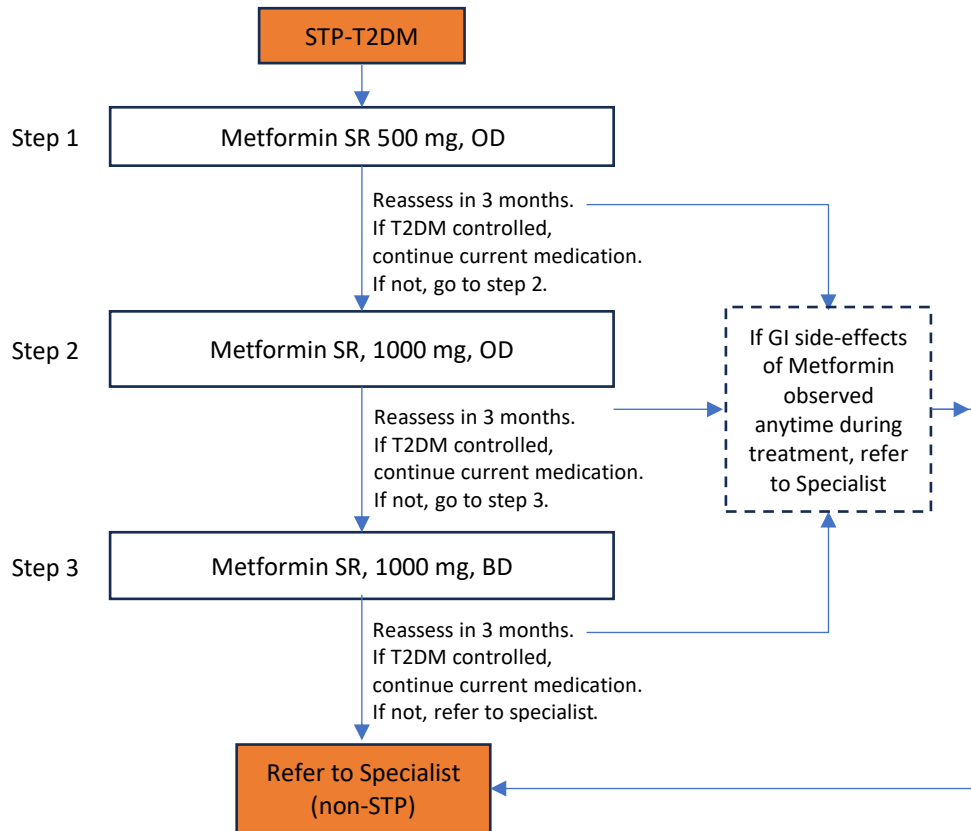


Figure 2: Treatment protocol of T2DM (adapted from WHO’s Package of Essential Noncommunicable [PEN] disease interventions for primary healthcare guidelines 2013)^c

BD, *bis in die* - twice daily; GI, gastro-intestinal; OD, *omne in die* - once daily; WHO-PEN, SR, sustained-release; STP, straight-through process; T2DM, type 2 diabetes mellitus.

^c Given the limitations of the care model and the low testing context, especially of complications, we decided to limit the straight through process in the NEEM program only until Metformin although WHO PEN protocol goes further.

3. T2DM Referral case

3.1 Eligibility

- RBS or FBS > 300 mg/dL
- On medication(s) for diabetes at time of screening
- Currently pregnant
- Is on dialysis
- Gastro-intestinal side effects of Metformin are observed
- Glycemic control is not observed despite adherence to STP-T2DM treatment for 9 months

3.1 Treatment

- Initiate pharmacological and non-pharmacological treatment:
 - HW must advise patient to go to nearest medical center immediately.
 - If patient refuses, HW must immediately inform DD over a phone call in the patient's presence. DD joins the teleconsultation session^d to advise patient for immediate visit to medical center. If the patient still cannot go to a medical center, DD will generate a prescription for Gliclazide 80 mg + Metformin 500 mg, twice daily, 1-0-1.
 - HW will make all reasonable efforts to get the patient to take the first dose in her presence. She will dispense the medicine from her stock.
 - HW will call the patient/caregiver the following day to check if medicines have been purchased and taken for the day.
 - HW will visit the patient again after a week to reassess RBS and check for hypoglycemia-related complaints. DD will be informed about the visit outcome.
 - Subsequently, this patient will be visited at least once a month until control has been achieved.
- Escalate: Refer to specialist. Turn-around-time between screening and sharing prescription with patient should be no longer than 10 days. The template used for such referral cases is depicted in [Annexure 4](#).

^d Refer to telemedicine consultations SOP here.

iv. Follow-up/Check-in Visits

- Upon treatment initiation, the HW will periodically follow-up on the patient to do the following:
 - Check RBS.
 - If controlled, schedule the next follow-up after 3 months.
 - If uncontrolled, check for adherence.
 - If non-adherent, counsel patient on importance and possible complications.
 - If adherent, follow draft prescription process for the next medicines as per WHO's PEN protocol until step 3. After this, mark case as non-STP. Go to section [3. T2DM Referral case](#).
- Check for other comorbidities. If other comorbidities present, mark the case as non-STP. Go to section [3. T2DM Referral case](#).
- If a patient complains of any other symptom, check if it matches with any complications listed in [Annexure 3](#) and direct the patient accordingly.

Data analysis

Auto-populated data on NEEM360 platform will be analysed for various outcomes on a regular basis. Periodic monitoring and evaluation will be performed.

Outcomes:

1. Number and percentage of active patients diagnosed with T2DM, by quarter of enrollment and by HW
2. Number and percentage of active patients whose RBS readings are under control after initiation of treatment, by quarter of enrollment and by HW
3. Number and percentage of active patients whose RBS readings have improved, but still not under control after initiation of treatment, by quarter of enrollment and by HW
4. Complications due to diabetes: number of new diabetes complications in the past year/ number of patients with diabetes in the past year

RBS measurements from the latest reading will be considered for analysis of outcomes. The data auditing will be performed weekly by the Clinical Operations Team. Outcomes will be analysed and published quarterly and annually.

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5. Pickering D, Marsden J. How to measure blood glucose. *Community Eye Health*. 2014;27(87):56-57.
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Standard Values and Definitions

Active patients	T2DM patients who are active subscribers of the NEEM program
Baseline RBS reading	RBS reading recorded at screening (first visit)
Controlled T2DM	Latest RBS reading <200 mg/dL ⁶
Follow-up/Check-in	Visit by HW after the initial screening visit to check on patients' status
Improved RBS reading	RBS reading towards the normal value of 200 mg/dL but lesser than baseline RBS reading
Latest RBS reading	RBS reading recorded in the most recent visit, which is at least 90 days since the earlier reading
Loss to follow-up	Patient not available for further visits or follow-ups
Subscriber	Individual who has subscribed to DHF's NEEM360

Annexures

Annexure 1: Care Model of NEEM Program

NEEM program's care model comprises a local health worker assigned to screen and monitor a fixed cohort of individuals at their homes under the supervision of a remotely located physician.

The HW has access to NEEM360, a technology platform that comprises of the following:

- i) Patient record
- ii) Embedded protocols for screening, treatment, and referrals
- iii) Medicine order module and
- iv) A summary dashboard.

Each HW is also provided a kit comprising all the necessary devices for measurement of vitals. HW will facilitate medicine delivery and sample collection at home. There is no facility-based care. Cases identified for referral are discussed by the physician with the relevant specialist on a virtual basis and the prescriptions amended as suitable.

Annexure 2: Human Resource Strategy of the NEEM Program

Health Worker (HW):

Eligibility: Local resident with a minimum educational qualification of having cleared high school.

Roles and responsibilities: HW is trained to proactively provide counseling on healthy lifestyle, highly evidence-based protocolized care, and intensive follow-up to the members assigned to her during house visits. She is assisted by a computerized decision support system and supervised by a remote doctor for these activities.

Training^e: A 4-day long onboarding will be conducted for freshly recruited HW. The HW will be trained in effective communication, accurate vitals measurements, appropriate use of other instruments in the NEEM360 kit, using NEEM360 platform, troubleshooting, medicine delivery and subscription pathways, among others. The training will be conducted using visual aids and a hands-on approach which includes mock sessions and assessments. Periodic refresher training is conducted every two months. Additionally, feedback sessions are held regularly and case-by-case to discuss cases and processes.

Digital Doctor (DD):

Eligibility: Physician from the same state of project and who is authorized to prescribe medications.

Roles and responsibilities: The DD provides physician oversight in the diagnosis and treatment of the health condition by engaging with the HW regularly and with patients via telemedicine in a team-based care approach. The data collected digitally by HW on the NEEM360 platform is accessible to the DD and assists in tracking patient's health and in decision-making.

Training: The physician will undergo reorientation and familiarize themselves with guidelines, protocols, SOPs mentioned in [Annexure 5](#). Hands-on training will be provided for usage of NEEM360 platform. Additionally, feedback sessions are held regularly and case-by-case to discuss cases and processes.

Specialist Coordinator: Physician authorized to prescribe medications, who will be the interface between a specialist and DD. The Specialist Coordinator will compile all referral cases and related information, obtain the opinion and treatment options from the specialist, and convey the same to the DD.

Specialist^f: A physician, usually a cardiologist, will look at referral cases, plan the treatment, and convey the same to the Specialist Coordinator.

^e Refer to HW training SOP here.

^f Refer to Specialist SOP here.

Annexure 3: Signs and symptoms of common complications encountered in patients and their management^{1,6}

Sl. No.	Signs and Symptoms	Probable Complication	Management
1.	<ul style="list-style-type: none"> • RBS<70 mg/dL • Headache, hunger, irritability, anxiety, feeling of tingling, numbness or “pins and needles, sensation that the heart is racing, pounding • Check if patient has following symptoms: sweating, trembling, difficulty in speaking, paleness, unsteadiness, confusion, seizures, coma 	Hypoglycemic condition	<ul style="list-style-type: none"> • If patient is conscious, give 15-20 g of glucose. If glucose is unavailable, give sugar/sugar sweetened soft drink/sweet candies/milk. • If patient is not conscious or unable to ingest food or drink, shift to nearest medical centre immediately.
2.	Altered consciousness, frequent nausea, vomiting, abdominal pain	Hyperglycemic emergencies*	Shift to nearest medical centre immediately.
3.	Change in vision or vision loss as stated by patient	Retinopathy (eye disease)	Refer to ophthalmologist at the earliest. In general, refer once every two years.
4.	High blood pressure, nausea, itching, anorexia, swelling in feet	Nephropathy (kidney disease)	Refer to specialist.
5.	Unsteadiness, feeling of burning, tingling, numbness or “pins and needles; lack of awareness of hypoglycemia; loss of control over urination	Neuropathy (nerve damage)	Refer to specialist.
6.	<ul style="list-style-type: none"> • Change in the color and temperature of the feet • Thickened, yellow toenails • Fungal infections between the toes • Boil, ulcer, infection or ingrown toenail • Loss of sense of touch or ability to feel heat or cold very well 	Foot problems	Refer to nearest medical centre immediately.

*Defined as a condition with high blood glucose levels characterised by RBS>325 mg/dL.

Annexure 4: Template for Referral Cases

Case No:

Date of screening:

Patient information:

Vitals:

Temperature: F	RBS: mg/dl
PR: /min	BMI:
BP: mmhg	Weight: kg
RR: /min	CVD risk score: %
Spo2: %	

Provisional Diagnosis:

Chief complaints:

Evaluation of screening findings

Past history: (chronic kidney disease, stroke, myocardial infarction, bronchial asthma, hypertension, type 2 diabetes mellitus)

H/o

NO h/o

Treatment:

Advice:

BMI, body mass index; BP, blood pressure; CVD, cardiovascular disease; PR, pulse rate; RBS, random blood sugar; RR, respiratory rate; SpO₂, saturation of peripheral oxygen.

Annexure 5: Training Material for Doctors

Mandatory Reading:

1. WHO package of essential noncommunicable (PEN) disease interventions for primary health care. <https://www.who.int/publications/i/item/9789240009226>
2. Guidelines for Telemedicine practice. <https://www.mohfw.gov.in/pdf/Telemedicine.pdf>

Recommended Reading: WHO HEARTS-D. Diagnosis and management of Type 2 Diabetes. <https://www.who.int/publications/i/item/who-ucn-ncd-20.1>