Protocol for Management of Hypertension

Prepared by Dr. Lakshmi Krishnan
Version 3 dated June 03, 2024.

Table of Contents

Acronyms and Abbreviations 2
Glossary 2
Introduction and Background 3
Objective of Dvara Health Finance's (DHF's) NEEM Program 3
Process Flow for HTN Management 4
i. Enrolment 4
ii. Assessment – Case History and Screening 4
iii. Diagnoses and Management 5
iv. Follow-up/Check-in Visits 9
Data analysis 9
References 10
Standard Values and Definitions 11
Annexures 12
Annexure 1: Care Model of NEEM Program 12
Annexure 2: Human Resource Strategy of the NEEM Program 13
Annexure 3: Training Material for Doctors 14

Acronyms and Abbreviations

BP	blood pressure
CVD	cardiovascular diseases
DBP	diastolic blood pressure
DD	digital doctor
DHF	Dvara Health Finance
HEARTS	Healthy-lifestyle counselling, Evidence-based treatment protocols, Access to essential medicines and technology, Risk-based CVD management, Team-based care, and Systems for monitoring
HW	health worker
HTN	hypertension
IHCI	India's Hypertension Control Initiative
SBP	systolic blood pressure
SOP	standard operating procedures
STP	straight through process
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
Hypertension	Defined as SBP≥140 mmHg and DBP≥90 mmHg. A person with hypertension is known as hypertensive

Introduction and Background

Cardiovascular diseases (CVDs) are the leading cause of deaths in India with 185 deaths per 100,000 population.[1] Hypertension (HTN), or high blood pressure, is the major risk factor for CVDs and is prevalent in around 30% of Indian population.[2,3] Yet, most of the population are unaware about the condition.[4] Of the estimated 20 crore hypertensive adults in India, less than two crores have it under control.[5] Lack of awareness, access to facilities and medicines are often reasons for the high prevalence of the condition.[6]

Figure 1: Mortality due to hypertension and burden in Indian population[5]

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 HTN 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 blood pressure (BP) by following the below guidelines:[3,7]
    a. Location: Noise-free, no talking, no TV/telephone/audio distractions
    b. Ask subscriber to empty bladder before test and to avoid tea/coffee, exercise, and tobacco use for 30 minutes before recording BP. Subscriber should be seated and relaxed, back supported, legs uncrossed, arms supported by book/pillow/desk etc. (figure 2)
    c. Device: Position cuff on subscriber's bare mid-upper arm and center it over brachial artery. Cuff should have snug fit, allowing only two fingers to fit between cuff and skin. The cuff should be at heart level.
    d. Normal BP value: Systolic BP (SBP) <140 mmHg and diastolic BP (DBP) <90 mmHg. If BP at first reading is above normal value, repeat measurements after 15-20 minutes.
    e. Record accurate readings without rounding them.
    f. Diagnosis of hypertension is established when SBP≥140 mmHg and/or DBP≥90 mmHg. The diagnosis is based on an average of the readings as calculated by NEEEM360.

Notes on BP measuring device:[3]

- It is recommended to use an automated non-invasive blood pressure measuring device with cuff which follows World Health Organisation's (WHO's) technical specifications. Refer here for complete document. The NEEM program currently uses a fully automatic digital blood pressure monitor by Beurer BM 35, which meets ISO 81060-2:2018 standards.
- Check integrity of cuff and tubing, and power source at least once a month if device is used daily. Routine maintenance to be carried out as per device manufacturer's guidance.
- Check device accuracy once a year against a well-maintained mercury sphygmomanometer.

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

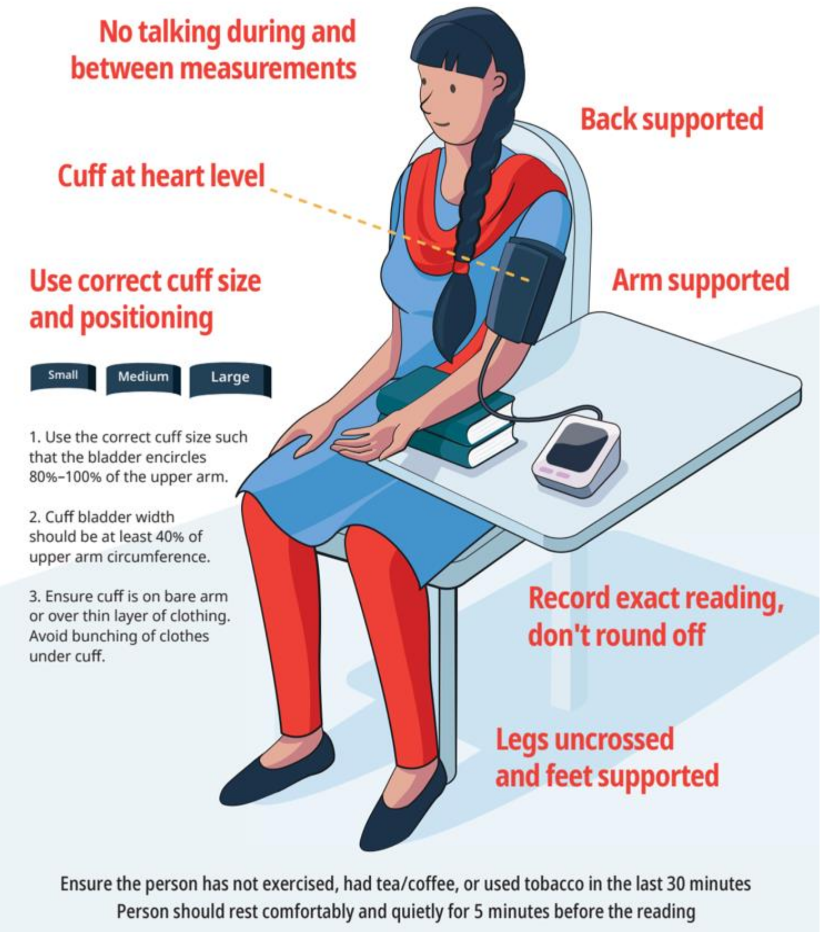

Figure 2: Checklist for recording BP measurement.[7]

iii. Diagnoses and Management

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

1. Non-hypertensive case
2. Hypertensive: Straight through process (STP), henceforth referred to as STP-HTN case
3. Hypertensive: Crisis case
4. Hypertensive: Referral case

An overview of the management is depicted in figure 3. The categories and respective management are described further below in the document.

1. Non-hypertensive case

If SBP is 130-139 mmHg and DBP is 80-89 mmHg (Stage 1 HTN) and no other CVD risk factors, verbal advice to limit salt intake and engage in physical activity for at least 30 minutes/day. Cases in this category would be revisited once in three months for re-measurement and monitoring.

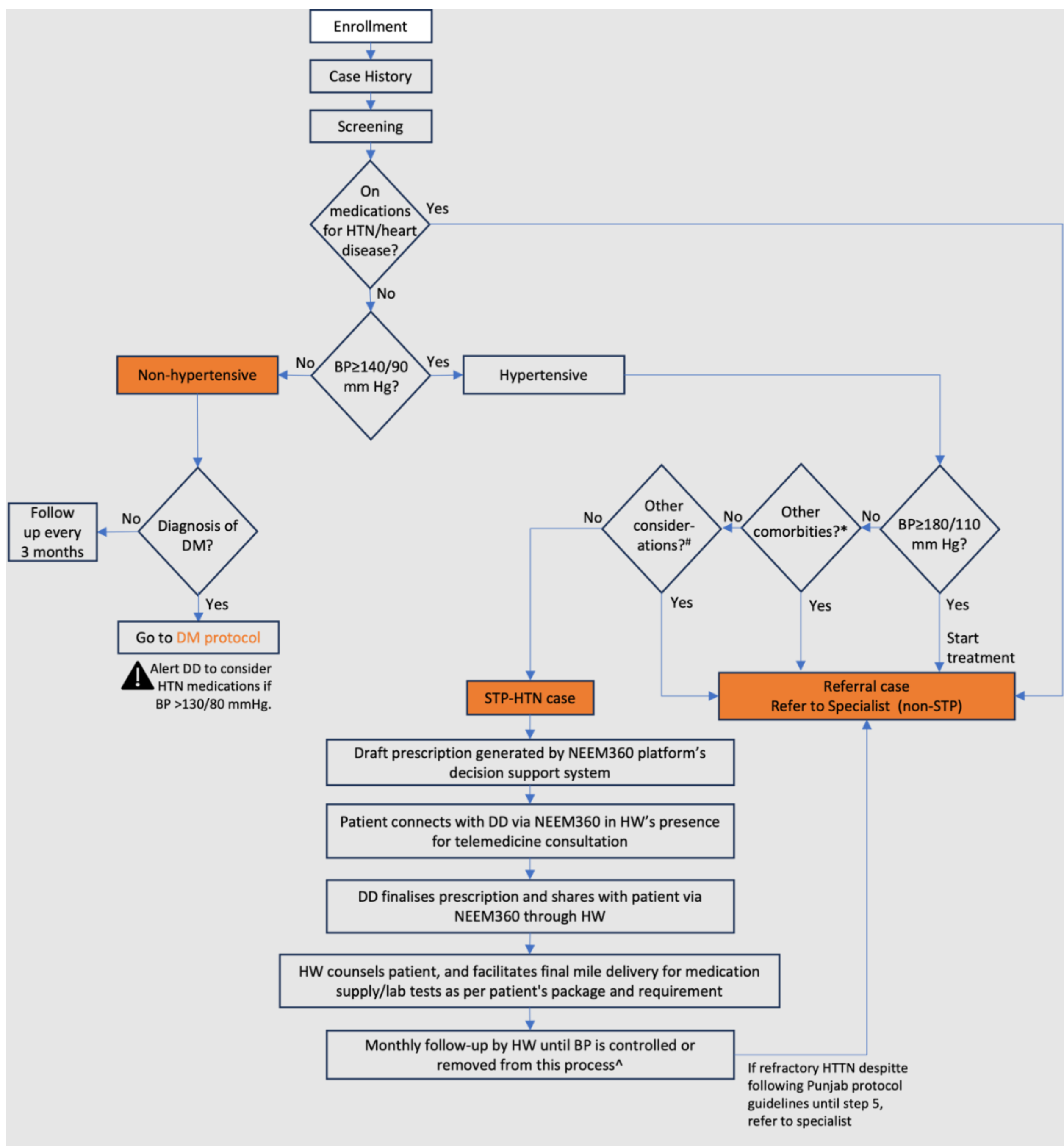

Figure 3: Management of hypertension in registered users of NEEM program

BP, blood pressure; DD, digital doctor; DM, diabetes mellitus; HW, health worker; HTN, hypertension; STP, straight-through process.

*Comorbidities: Prior diagnosis/history of HTN or other heart diseases (myocardial infarction/stroke); symptoms indicating angina, heart failure; WHO cardiovascular disease (CVD) risk status ≥20%.
#Other considerations: Pregnant or planning for pregnancy
^Migration/death/discontinued subscription etc.

2. STP-HTN case

2.1 Eligibility

- Not on medication(s) for HTN or heart diseases at the time of screening
- No known or apparent co-morbidities or other considerations that would require delving into their medical history in greater detail such as:
  - Pregnancy: currently pregnant, or planning for pregnancy, or inadequate birth control measures
  - BP>140/90 mmHg and <180/110 mmHg (hypertensive crisis)
  - Prior diagnosis/history of HTN or other heart diseases (myocardial infarction/stroke)
  - Symptoms indicating angina, heart failure
  - WHO CVD risk status ≥20%

If any one of the above criteria apply to the patient, go to section 4. Referral case.

2.2 Treatment

- Initiate pharmacological treatment as per Punjab protocol guidelines in Annexure 3.[b]
  - 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.[c]
  - DD finalises prescription and shares it with patient via the NEEM360 platform through HW. Turn-around time targeted between screening and sharing prescription with patient is no more than 48 hours.
  - In case DD rejects the automatic prescription, case is marked as non-STP and DD documents reason(s) for the rejection on NEEM360.
  - HW counsels patient on healthy diet, physical activity, the harms of tobacco use, and harmful use of alcohol.
  - HW facilitates the final mile delivery for medication supply as per patient's package, and requirement(s).
  - Follow-up at least once every month by HW until SBP<140 mmHg or removed from this process (migration/death/discontinued subscription).
- Escalate:
  - If any of the comorbidities listed in 2.1 apply to the patient, mark case as non-STP. Go to section 4. Referral case.
  - If refractory HTN despite following Punjab protocol guidelines until step 5, mark the case as non-STP. Go to section 4. Referral case.

---

[b] The Punjab protocol guidelines[8] issued by India's Hypertension Control Initiative (IHCI) is based on WHO's Global Monitoring Framework and the HEARTS initiative.
[c] Refer to telemedicine consultations SOP here.

- If BP≥180/110 mmHg at screening or despite change in medication and adherence, mark case as Hypertensive Crisis. Go to section 3. Hypertensive Crisis case.[d]

3. Hypertensive Crisis case

3.1 Eligibility*:* BP≥180/110 mmHg at screening or despite change in medication and adherence

3.2 Treatment:

- Advise patient to relax. Re-measure BP after a duration of 20 minutes. If BP continues to be ≥180/110 mmHg:
  - 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.[c] DD joins the teleconsultation session to advise patient for immediate visit to medical center. This will be done on a recorded line via NEEM360 platform.
  - If the patient still cannot go to a medical center, DD will generate a prescription for Amlodipine 5 mg + Telmesartan 40 mg once daily.
  - 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 and measure BP again in 5 days.
  - Subsequently, this patient will be visited at least once a month until control has been achieved.
- Escalate: If the BP continues to be ≥180/110 mmHg, then go to section 4. Referral case.

4. Referral case

4.1 Eligibility

- On medication(s) for HTN or heart diseases at time of screening and yet has uncontrolled BP
- Comorbidities or considerations listed in 2.1 apply
- Refractory HTN despite following Punjab protocol guidelines until step 5

4.2 Treatment: Refer to specialist. Targeted turn-around time between screening and sharing prescription with patient is 10 days. The template used for such referral cases is depicted in Annexure 4.

[c] Refer to telemedicine consultations SOP here.
[d] This is as per the American Health Association (AHA)[9] and local practices.

iv. Follow-up/Check-in Visits

Upon treatment initiation, the HW will periodically follow-up on the patient to do the following:

- Check BP.
  - If controlled, schedule the next follow-up after 1 month.
  - If uncontrolled, check for adherence.
    - If non-adherent, counsel patient on importance and possible complications.
    - If adherent, draft prescription process for the next medicines as per Punjab protocol. At step 5 of India Hypertensive Control Initiative's Punjab protocol, if BP is still uncontrolled, mark the case as non-STP. Go to section 4. Referral case.
- Check for other comorbidities (diabetes mellitus etc). If other comorbidities present, mark the case as non-STP. Go to section 4. Referral case.

Data analysis

Data that is auto-populated 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 HTN, by quarter of enrollment and by HW
2. Number and percentage of active patients whose BP readings are under control after initiation of treatment, by quarter of enrollment and by HW
3. Number and percentage of active patients whose BP readings have improved (Stage 2 HTN), but still not under control after initiation of treatment, by quarter of enrollment and by HW

BP 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.

References

1. GBD Compare [Internet]. Institute for Health Metrics and Evaluation. [cited 2024 Jan 19]. Available from: https://vizhub.healthdata.org/gbd-compare/
2. India State-Level Disease Burden Initiative Collaborators. Nations within a nation: variations in epidemiological transition across the states of India, 1990-2016 in the Global Burden of Disease Study [published correction appears in Lancet. 2017 Dec 2;390(10111):e49]. Lancet. 2017;390(10111):2437-2460. doi:10.1016/S0140-6736(17)32804-0
3. WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff. Geneva: World Health Organization; 2020.
4. Koya SF, Pilakkadavath Z, Chandran P, et al. Hypertension control rate in India: systematic review and meta-analysis of population-level non-interventional studies, 2001-2022. Lancet Reg Health Southeast Asia. 2022;9:100113. Published 2022 Nov 23. doi:10.1016/j.lansea.2022.100113.
5. IHCI factsheet [Internet]. India Hypertensive Control Initiative. [cited 2024 Jan 19]. Available from: https://www.ihci.in/resources/hypertension-best-practices/ihci-factsheet
6. Kaur P, Kunwar A, Sharma M, et al. The India Hypertension Control Initiative-early outcomes in 26 districts across five states of India, 2018-2020. J Hum Hypertens. 2023;37(7):560-567. doi:10.1038/s41371-022-00742-5
7. IHCI Training Modules [Internet]. India Hypertensive Control Initiative. [cited 2024 Jan 19]. Available from: https://www.ihci.in/resources/training-modules
8. IHCI State Hypertension Protocols. Punjab Hypertension Protocol [Internet]. India Hypertensive Control Initiative. [cited 2024 Jan 19]. Available from https://www.ihci.in/resources/protocols Whelton PK, Carey RM, Aronow WS, et al. 2017
9. ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2018;138(17):e484-e594. doi:10.1161/CIR.0000000000000596.

Standard Values and Definitions

Active patients	Hypertensive patients who are active subscribers of the NEEM program
Baseline BP reading	BP reading recorded at screening (first visit)
Brachial artery	A major artery in the upper arm, which is compressed by the BP cuff during BP measurement.
Controlled BP	Defined as BP<140/90 mmHg after medication from most recent reading[6]
Diastolic BP (DBP)	The pressure in blood vessels when the heart rests between beats.
Follow-up/Check-in	Visit by HW after the initial screening visit to check on patients' status
Hypertensive crisis	≥180/110 mmHg. Also referred to as Stage 3 HTN[9]
Improved BP reading	BP reading towards the normal value of 140/90 mmHg but lesser than baseline BP reading
Latest BP reading	BP reading recorded in the most recent visit, which is at least 30 days since the first reading
Loss to follow-up	Patient not available for further visits or follow-ups
Stage 1 HTN	SBP is 130–139 mmHg or DBP is 80–89 mmHg[9]
Stage 2 HTN	SBP≥140/90 mmHg[9]
Subscriber	Individual who has subscribed to DHF's NEEM360
Systolic BP (SBP)	The maximal pressure in the aorta when the heart contracts and ejects blood from the left ventricle

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 3. 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: Training Material for Doctors

Mandatory Reading:

1. Punjab HTN Protocol[8]: This protocol is followed for STP-HTN cases until step 5, after which refractory HTN cases are marked as non-STP and referred to a specialist.

2. Guidelines for Telemedicine practice. https://www.mohfw.gov.in/pdf/Telemedicine.pdf

Recommended Reading:

1. WHO package of essential noncommunicable (PEN) disease interventions for primary health care. https://www.who.int/publications/i/item/9789240009226
2. Indian Hypertension Control Initiative. https://www.ihci.in/

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: