HEARTS

Technical package for cardiovascular disease management in primary health care

Tool for the development of a consensus protocol for treatment of hypertension

World Health Organization

WHO/NMH/NVI/19.8

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Context

High blood pressure kills more people than any other condition – approximately 10 million people each year, more than all infectious diseases combined. Reducing blood pressure prevents stroke, heart attack, kidney damage, and other health problems.

An estimated 1.4 billion people worldwide have high blood pressure, but just 14% have it under control – that is roughly one person in seven. However, health providers in high- and low-income countries, urban and rural areas, and across different health systems show that a higher level of control can be achieved. Canada has reached nearly 70% control nationwide, and Barbados and Malawi have shown it is possible to increase control rates rapidly.

Health systems that are successful in supporting their patients to bring blood pressure under control do so by ensuring provision of a technical package with five key components:

1. treatment protocols that establish a standard dose- and drug-specific treatment of patients that is simple and practical yet provides sufficient detail, including specific medications and dosages and a schedule for titration or the addition of medications if blood pressure is uncontrolled
2. community-based care and task sharing so the health care workers who are most accessible to patients can provide care, including adjusting and intensifying medication regimens that follow doctor-directed protocols, allowing every member of the health care team to be optimally involved in supporting patient care
3. a regular and uninterrupted supply of quality-assured medications and equipment for accurate monitoring of blood pressure
4. patient-centered services that reduce barriers to adherence, including low-cost or free medical visits and medications; convenient medical visits and medication refills; once-daily treatment regimens with three-month refills for stable patients; the use of fewer tablets through combination medications; ready access to free blood pressure monitoring; and public education to increase awareness of the importance of controlling blood pressure
5. information systems that allow for real-time feedback on adherence and blood pressure control of individual patients, assessment of control rates by different treatment systems to strengthen tracking and accountability and facilitate continuous programme improvement.

The need for a standardized protocol

The creation and endorsement of a detailed and standardized treatment protocol is a critical first step in developing a successful large-scale hypertension programme. Standardized drug- and dose-specific treatment protocols have been shown to be superior to individualized treatment, and also facilitate the logistics of drug procurement, task sharing, staff training, data collection, and quality reporting.

Effective protocols have:

- fewer branching and more linear pathways
- fewer options and more direction
- fewer drug classes and more specific drugs
- fewer drugs names and more drug doses
- fewer single drug pills and more fixed-dose combinations.

As more experience with treatment of hypertension is gained, it has become clear that the great majority of patients can be effectively treated with a single protocol.

There are many examples of evidence-based hypertension treatment protocols, such as those listed in the *WHO HEARTS technical package module Evidence based protocols*. Using these and other published protocols, with a focus on assessing the suitability for use in the local context, it is possible to develop a consensus protocol appropriate for their country or subnational area.

Steps for the development of a consensus protocol

STEP 1: AGREEMENT AND APPOINTMENTS

- gain agreement of Ministry of Health (MoH) to develop a protocol
- establish MoH or local government sponsor
- appoint focal point person
- form technical working group

STEP 2: PREPARATION

- set up a panel of experts
- collate evidence-based protocol samples
- obtain information on:
  - access to and cost of medicines
  - current practice of prescription, BP measurement, outcome monitoring

STEP 3: APPROACH PAPER

- develop an approach paper and options with the technical working group and experts

STEP 4: CONSENSUS MEETING

- invite participants
- facilitate discussion
- arrive at consensus

STEP 5: DESIGN, ENDORSEMENT AND DISTRIBUTION OF PROTOCOL

- design a drug- and dose-specific protocol, taking into account:
  - the delivery platform
  - access to medicines
  - prescription rights
- obtain endorsement from the appropriate authority
- distribute to all relevant parties

STEP 1: AGREEMENT AND APPOINTMENTS

- gain agreement of Ministry of Health (MoH) to develop a protocol
- establish MoH or local government sponsor
- appoint focal point person
- form technical working group

Development of the protocol should start with the appropriate authority issuing a statement confirming sponsorship and expectations. This order/act/guidance will add credibility to the work and will ensure that the work has been started with due clearance by and agreement of the concerned administration. This confirmation can be at the level of the national ministry of health or at sub-national levels.

A written order indicating the name of a focal person, preferably a recognized key stakeholder, such as a professor of medicine or cardiology in a medical school, or a senior internal medicine specialist in a referral hospital, can help in bringing the experts together.

A technical working group should be established, consisting of multidisciplinary team members, such as a programme manager, pharmacist, primary care provider, medical specialist, chief nursing officer, and health information officer.

STEP 2: PREPARATION

- set up a panel of experts
- collate evidence-based protocol samples
- obtain information on:
  - access to and cost of medicines
  - current practice of prescription, BP measurement, outcome monitoring

It is critical to have key experts on the panel. They can be from teaching hospitals and other major hospitals, and may be cardiologists, nephrologists, or other appropriate medical specialists.

The panel should identify any existing protocols in the country. Sample protocols in WHO HEARTS E module or other sources can be used for adaptation.

Information on current hypertension clinical practice is important.

Information on the availability and type of BP devices used, cost of medicines, rates of stock outs, prescription practices, and other background data is useful to have at the consensus conference.

STEP 3: APPROACH PAPER

- develop an approach paper and options with the technical working group and experts

The approach paper is a dossier with all the relevant materials and information. This should be developed by the technical working group. It should include:

- government order with timeline and expectations
- current status of BP measurement and management in the country/state
- national hypertension and other relevant protocols
- data describing the availability of medicines and cost
- sample protocols from E module and protocols from other relevant sources.

STEP 4: CONSENSUS MEETING

- invite participants
- facilitate discussion
- arrive at consensus

The meeting should be planned with sufficient notice to allow participation of all the relevant experts

An external facilitator can be helpful.

Consider including state/province/district health programme managers in the areas of: primary care, NCD treatment, and access to medications; medication procurement agency personnel working in stock control and distribution; academics and leading physicians; and healthcare providers from the facility.

Sessions that can be considered during the meeting are:

- current status of hypertension treatment including protocols
- presentation on algorithms for hypertension management
- group work – discussion of proposed protocols
- finalizing the protocol and reaching consensus.

If possible, it is preferable to have a meeting for two days, although if preparation is good a single day may suffice. Start with government stating the need for the protocols and the current status, on the basis of the approach paper. Consider:

- the benefits of a standard protocol
- current practice for hypertensive patients
- availability and costs of hypertensive medications
- exploration of current supply-chain mechanism for anti-hypertensives
- special considerations for the population of the country.

Consider establishing sub-groups on diagnosis, management of and access to medicines and technology.

Plan to agree on the protocol during the second day.

Considerations should include whether it is evidence based, any local issues such as availability and cost.

Arrive at agreement on a specific drug- and dose-specific protocol that is easy to follow.

STEP 5: DESIGN, ENDORSEMENT AND DISTRIBUTION OF PROTOCOL

- design a drug- and dose-specific protocol, taking into account:
  - the delivery platform
  - access to medicines
  - prescription rights
- obtain endorsement from the appropriate authority
- distribute to all relevant parties

Design and share the endorsed protocol. Ensure that appropriate government endorsement and other details are provided to ensure that it is has been officially endorsed. Examples of consensus protocols developed in India are included in the Annex.

Develop a guide for implementation, with training needs, estimated quantity of required medicines, agreement on prescription privileges based on position for initiation and for refills, and definition of referral criteria.

Ensure wide dissemination such that the protocol reaches all appropriate staff, including central supply-store personnel, all doctors who are expected to provide services, nurses, and all health care providers who care for people with hypertension.

Provide as single-page, easy-to-use protocols.

Develop wall charts where needed and communicate widely.

Annex: Consensus protocols developed by states in India

Maharashtra

Hypertension Protocol

सार्वजनिक आरोग्य विभाग
महाराष्ट्र शासन

Measure blood pressure of **all adults** over 18 years

High BP: **SBP ≥ 140** or **DBP ≥ 90** mmHg

Check for compliance at each visit before titration of dose or addition of drugs

Step 1 — If BP is high*
Prescribe Amlodipine 5 mg + adherence counseling

Step 2 — After 30 days measure BP again. If still high:
Add Telmisartan 40mg**

Step 3 — After 30 days measure BP again. If still high:
Increase Telmisartan to 80mg

Step 4 — After 30 days measure BP again. If still high:
Increase Amlodipine to 10mg

Step 5 — After 30 days measure BP again. If still high:
Add Chlorthalidone 6.25mg

Step 6 — After 30 days measure BP again. If still high:
Increase Chlorthalidone to 12.5mg

... After 30 days measure BP again. If still high:
Check that patient has been taking drugs regularly and correctly. If so, refer patient to a specialist.

Women who are or could become pregnant

- ▲ DO NOT give Telmisartan or Chlorthalidone.
- ACE inhibitors, angiotensin receptor blockers (ARBs), thiazide/thiazide like diuretics and statins should not be given to pregnant women or to women of childbearing age not on highly effective contraception.
- Calcium channel blocker (CCB) can be used. If not controlled with intensification dose, refer to specialist.

Diabetic patients

- Treat diabetes according to protocol.
- Aim for BP target of <140/90.

Heart attack in last 3 years

- Add beta blocker to Amlodipine at initial treatment.

Heart attack or stroke ever

- Begin low-dose aspirin (75 mg) and statin.

Chronic kidney disease

- ACE inhibitor or ARB preferred if close clinical and biochemical monitoring possible after specialist opinion.

* **If SBP 140-159 and/or DBP 90-99**, start on lifestyle management for one month prior to initiation of medications.

If SBP ≥180 and/or DBP ≥110 start treatment and refer to specialist immediately.

Recommended investigations at initiation of therapy: CBC, blood sugar, serum creatinine, electrolytes (optional). If S creatinine >1.5 mg, refer to specialist.

** **If Telmisartan not available:** replace with Enalapril 5 mg (initiation dose) and 10 mg (intensification dose).

Lifestyle advice for all patients

- Eat less than 1 tsp of salt per day: avoid papads, chips, chutneys, dips, pickles, etc.
- If overweight, lose weight.
- Exercise regularly: 2.5 hours per week
- Avoid alcohol and tobacco
- Limit intake of fried foods.
- Avoid foods with high amounts of saturated fats (e.g. cheese, ice cream, fatty meat).
- Avoid processed foods containing trans fats.
- Avoid added sugar.
- Eat 5 servings of fruits and vegetables per day.
- Use healthy oils: polyunsaturated and monounsaturated oils.
- Reduce fat intake by changing how you cook: remove the fatty part of meat; use vegetable oil; boil, steam or bake rather than fry; limit reuse of oil for frying.

India Hypertension Management Initiative:
Maharashtra 1.00-9-18

Punjab

Hypertension Protocol

Measure blood pressure of **all adults** over 18 years

High BP: **SBP ≥ 140** or **DBP ≥ 90** mmHg

Step 1
If BP is high:*
Prescribe Amlodipine 5mg

Step 2
After 30 days# measure BP again. If still high:
Increase to Amlodipine 10mg

Step 3
After 30 days# measure BP again. If still high:
Add Telmisartan 40mg

Step 4
After 30 days# measure BP again. If still high:
Increase to Telmisartan 80mg

Step 5
After 30 days# measure BP again. If still high:
Add Chlorthalidone 12.5mg**

Step 6
After 30 days# measure BP again. If still high:
Increase to Chlorthalidone 25mg**

...
After 30 days measure BP again. If still high:
Check if the patient has been taking medications regularly and correctly. If yes, refer to a specialist.

Pregnant women and women who may become pregnant

- ▲ DO NOT give Telmisartan or Chlorthalidone.
- – Statins, ACE inhibitors, angiotensin receptor blockers (ARBs), and thiazide/thiazide-like diuretics should not be given to pregnant women or to women of childbearing age not on effective contraception.
- – Calcium channel blocker (CCB) can be used. If not controlled with intensification dose, refer to a specialist.

Diabetic patients

- – Treat diabetes according to protocol.
- – Aim for a BP target of < 140/90 mmHg.

Heart attack in last 3 years

- – Add beta blocker to Amlodipine with initial treatment.

Heart attack or stroke, ever

- – Begin low-dose aspirin (75mg) and statin.

People with high CVD risk

- – Consider aspirin and statin.

Chronic kidney disease

- – ACEI or ARB preferred if close clinical and biochemical monitoring is possible.

* If SBP ≥ 180 or DBP ≥ 110, refer patient to a specialist after starting treatment.
If SBP 160-179 or DBP 100-109, start treatment on the same day.
If SBP 140-159 or DBP 90-99, check on a different day and if still elevated, start treatment.

\# Dose of anti-hypertension medications can be titrated at 15 days frequency if required.

** Hydrochlorothiazide can be used if Chlorthalidone is not available (25 mg starting dose, 50 mg intensification dose).

Lifestyle advice for all patients

Avoid tobacco and alcohol | Exercise 2.5 hours/week | Reduce weight, if overweight | Reduce salt, under 1 tsp/day | Eat less fried foods

- Eat 5 servings of fruits and vegetables per day.
- Avoid papads, chips, chutneys, dips, and pickles.
- Use healthy oils like sunflower, mustard, or groundnut.

Limit consumption of foods

- containing high amounts of saturated fats.
- Reduce fat intake by changing how you cook:
  - Remove the fatty part of meat
  - Use vegetable oil
  - Boil, steam, or bake instead of fry
  - Limit reuse of oil for frying
- Avoid processed foods containing trans fats.
- Avoid added sugar.

India Hypertension Management Initiative: Punjab 1.00-5-15

Resources

Technical package for cardiovascular disease management in primary health care. Evidence-based treatment protocols https://apps.who.int/iris/bitstream/handle/10665/260421/WHO-NMH-NVI-18.2-eng.pdf;jsessionid=1668E30A538A5066985C863BE6CB5973?sequence=1

RESOLVE TO SAVE LIVES.
https://www.resolvetosavelives.org/saving-lives-from-cvd