

Technical package for cardiovascular disease management in primary health care









Noternational Society of Hypertension







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International Society of Hypertension





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### **Table of contents**

Abbreviations	6
Preface	8
Introduction	11
Rationale and strategic approach	15
Scope of HEARTS	21
Elements of HEARTS	23
Healthy lifestyle	25
Evidence-based treatment protocols	29
Access to essential medicines and technology	33
Risk-based management	37
Team care and task-sharing	43
Systems for monitoring	49
Approach to implementation	53
References	56
Annex 1. Evidence-based protocols	60
<ul> <li>a. Protocol for prevention of heart attacks, strokes and kidney disease within integrated management of diabetes and hypertension (WHO-PEN protocol 1)</li> </ul>	60
b. Health education and counselling on healthy behaviour (WHO-PEN protocol 2)	64
c. Tobacco cessation counselling protocol	66
d. Self-care among patients with CVD or diabetes (WHO-PEN protocol 5)	67
Annex 2. Essential medicines and basic technology for implementing CVD interventions in primary health care	69
a. Core list of medicines required for implementing essential CVD interventions in primary care	69
b. Core list of basic technology and tools for implementing essential CVD interventions in primary care	70
Annex 3. WHO and International Society of Hypertension cardiovascular	
risk prediction charts	71
Annex 4. Clinical and process indicators for implementation of HEARTS	72

### **Abbreviations**

CDC	Centers for Disease Control and Prevention (United States)
CVD	cardiovascular disease
HIV	human immunodeficiency virus
ISH	International Society of Hypertension
LMICs	low- and middle-income countries
NCD	noncommunicable disease
РАНО	Pan American Health Organization
WHO	World Health Organization
WHO-PEN	WHO Package of Essential Noncommunicable Disease Interventions
	for Primary Health Care in Low-resource Settings

#### **Measurements**

cm	centimetre
dL	decilitre
L	litre
mg	milligram
mmHg	millimetre of mercury
mmol	millimole



### Preface

Nearly everyone reading this document has been affected by cardiovascular disease (CVD) in some way, either personally or through someone they know. If current trends continue, the annual number of deaths from CVD will rise from 17.5 million in 2012 to 22.2 million by 2030.

Four of five people who die from CVD are killed by a heart attack or a stroke, and one third of these deaths occur in people under 70 years of age. Heart attacks and strokes, which are often avoidable outcomes, cause a lot of suffering for individuals and families affected. They also impose a substantial cost on society, particularly in low- and middle-income countries (LMICs), where over three quarters of deaths from these conditions occur. Millions of people worldwide struggle to control the risk factors that lead to cardiovascular disease, many others remain unaware that they are at high risk. A large number of heart attacks and strokes can be prevented by controlling major risk factors through lifestyle interventions and drug treatment where necessary.

Improvements in prevention and treatment have led to decreases in the rates of CVD in many high-income countries but similar trends have not been seen in many other parts of the world where the burden is greatest. The world's leaders committed themselves to ambitious reductions in premature CVD deaths in the United Nations 2030 Agenda for Sustainable Development, the World Health Organization (WHO) Global Action Plan for the Prevention and Control of Noncommunicable Diseases (NCDs) 2013-2020 and the Political Declaration of the High-level Meeting of the United Nations General Assembly on NCDs. Bold action to scale up services across the spectrum of prevention and management of risk factors is necessary to reach these targets.

The HEARTS technical package provides a set of effective, practical interventions for strengthening the management of risk factors for CVDs in primary health care. The aim is to prevent cardiovascular disease (heart attacks and strokes) by ensuring equitable access to continuous, standardized, high-quality care for people at high risk. HEARTS is aligned with and builds on the WHO *Package of Essential Noncommunicable Disease Interventions for Primary Health Care in Low-resource Settings* for strengthening NCD management, and it complements WHO strategies and packages for population-based primary prevention of CVD, including tobacco control and salt reduction.

HEARTS represents an unprecedented alignment among stakeholders in global CVD management. It responds to the agreement that sustainable, effective action is urgently required to prevent cardiovascular diseases. Millions of lives could be saved through the implementation of the HEARTS package.

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### Introduction

More people die from cardiovascular diseases (CVDs) worldwide than from any other cause – an estimated 17.5 million people in 2012. Of these deaths, 80% are due to heart attacks and strokes, and over three quarters occur in low- and middle-income countries (LMICs) (1). In 2012, 34% of CVD deaths occurred in people under 70 years of age (1). CVDs disproportionately affect LMICs, and in many countries the economic and social burden is highest amongst poor and disadvantaged groups.

The risk factors for CVD include behavioural factors, such as tobacco use, an unhealthy diet, harmful use of alcohol and inadequate physical activity, and physiological factors, including high blood pressure (hypertension), high blood cholesterol and high blood sugar or glucose which are linked to underlying social determinants and drivers (Fig. 1).

#### Fig. 1. Factors contributing to the development of cardiovascular disease and complications



Source: WHO Package of essential noncommunicable disease interventions (8).

Hypertension is a major risk factor and key driver of CVD globally and is estimated to have caused 9.4 million deaths in 2010 but remains widely undetected, undertreated and poorly controlled (2). Furthermore, a significant number of people with prior heart disease or stroke do not have access to essential medicines, such as aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors which have proven to be effective to prevent recurrent events and reduce mortality (3). The increase in the burden of CVDs in LMICs is driven by both an increased prevalence of risk factors and a relative lack of access to medical care in often underresourced health systems (4).

Effective methods for reducing the burden of CVD include population-wide interventions to reduce overall risk factor exposure, individual approaches to modify risk factors for high-risk individuals (including people with diabetes) and treatment of CVD events. In 2013, the World Health Assembly endorsed nine voluntary global targets for noncommunicable diseases (NCDs) to be achieved by 2025 through these approaches, including the overall target of reducing premature mortality from NCDs by 25% by 2025 ( $25 \times 25$ ). If current trends continue, most regions will see continued increases in the number of deaths from CVDs (Fig. 2). However, if all the proposed global risk factor targets are achieved, at least 2 million premature deaths could be averted each year, with most of the benefits seen in LMICs (*5*). These gains could be amplified by additional actions on treatment and strengthening of the health-care system leading to improved quality of life and productivity. Concerted, evidence-based action to prevent CVD is essential to attain  $25 \times 25$  and, beyond that, to reach the United Nations Sustainable Development Goal of reducing premature NCD mortality by one third by 2030.



Fig. 2. Projected CVD deaths 2015-2030 by WHO region

AFR, African Region; AMR, Region of the Americas; EMR, Eastern Mediterranean Region; SEAR, South-East Asia Region; WPR, Western Pacific Region

Source: WHO Global health estimates 2014 (1).





### **Rationale and strategic approach**

Most premature deaths due to CVD can be avoided. Many high-income countries have seen significant decreases in age-adjusted CVD mortality rates with a combination of preventive interventions to avert disease, early treatment to prevent death during acute events (heart attacks and strokes) and treatment to prevent recurrent events and to prolong the lives of people with prior CVD. Reductions in the burden of modifiable CVD risk factors are estimated to contribute as much as 50% to the observed decrease in mortality from CVDs in high-income countries, reflecting a combined impact of population interventions to reduce risk factors and clinical treatment (*6*).

Scaling up the implementation of evidence-based clinical interventions for CVD prevention in high-risk individuals could significantly reduce the number of premature CVD deaths in LMICs with only a modest initial increase in health expenditure (7). Such interventions, deployed using an integrated, comprehensive approach in primary health care, constitute the front line for service delivery to scale up CVD management.

In the primary health care setting, the focus should be on:

- primary prevention to avert disease by addressing major modifiable risk factors, including tobacco use, hypertension, high blood cholesterol and diabetes, using a total cardiovascular risk approach;
- secondary prevention to prevent recurrent events in people with a history of CVD; and
- early detection of acute manifestations of CVD (acute heart attacks and strokes), with prompt referral to the next level of care.

The World Health Organization (WHO) has recommended a package of essential NCD interventions (WHO-PEN), with protocols and tools for NCD management (including management of cardiovascular risk) in primary health care (8). The package includes simple, affordable tools (e.g. clinical measurements, simple laboratory testing, CVD risk assessment charts, blood pressure measurement devices) for early detection and treatment. As CVD is clinically asymptomatic in the early stages, these tools should be used proactively to identify people at risk for heart attacks or strokes and to improve their outcomes with a targeted screening approach in various settings.

Currently, too few services are offered in primary health care and, when available, they are typically unstructured, inadequate and may not be evidence based (9). This gap between evidence and current practice in LMICs is due to weak health systems and limited resources for NCD management, competing priorities, lack of standardized protocol-based management, inadequate access to affordable essential medicines and basic technology, and lack of data for monitoring outcomes.

Health systems should be reoriented and strengthened to respond effectively to the increasing burden of CVD with a patient-centred system for chronic care that is proactive, community based and sustainable. Such care can be delivered equitably starting in primary health care, which is the entry point for care for most people. This approach improves coverage and equity and over time can result in better health outcomes at lower cost by avoiding the expense associated with complications of CVD. It can also contribute to the framework for managing other chronic diseases.

Premature deaths from CVDs in LMICs can be prevented by comprehensive management of cardiovascular risk factors in primary health care



#### Technical package for CVD management in primary health care

The HEARTS technical package represents a strategic and practical approach to reducing the number of premature deaths from CVD. The aim is to improve clinical preventive services in primary health care using highly effective, scalable, sustainable and proven interventions. It involves a public health approach to CVD management that will improve access, particularly in settings with significant resource limitations, by systematically addressing barriers to care. The main conceptual shift is the use of a protocol-driven approach to simplify, standardize and support the scaling-up of integrated CVD management in countries. The public health approach involves:

- simplified treatment with standard protocols for primary and secondary prevention and appropriate referral, using a core set of medicines and basic technology; and
- improved cascade of service delivery by task-sharing and robust clinical monitoring.

Similar strategies have been used successfully to scale up tuberculosis treatment and antiretroviral therapy for the treatment and care of patients with HIV (10). The HEARTS technical package is fully aligned with and complementary to the clinical guidance provided in the WHO-PEN.

#### The HEARTS technical package covers six elements



#### **HEARTS** supports implementation of WHO-PEN protocols

The HEARTS technical package offers a framework for implementing the integrated management of NCDs in the WHO-PEN, which includes a set of cost-effective interventions that represent the minimum standard for NCD management in countries. The WHO-PEN protocols for management of CVD and diabetes (protocol 1) and the cross-cutting lifestyle management protocol (protocol 2) are the key protocols in the HEARTS technical package. HEARTS addresses the four main risk factors (tobacco use, physical inactivity, unhealthy diets and harmful alcohol use) and two major diseases (CVD and diabetes). The implementation tools in the HEARTS technical package allow a modular approach for adapting and including other components of NCD management (Fig. 3). The HEARTS package is presented as the first step in building an integrated NCD programme in primary health care; it does not promote a vertical or silo approach for CVD management alone.



#### Fig. 3. Modular approach to implementing the WHO-PEN components

Source: WHO Package of essential noncommunicable disease interventions (8).

The HEARTS package enhances implementation of the WHO-PEN protocols by providing the technical and operational outline and tools necessary for integrating CVD management into primary health care and for evaluating the impact. It builds on some of the tools in the WHO-PEN and provides additional tools for training, patient and programme monitoring and implementation (Table 1).

#### Table 1. Comparison of tools in the WHO-PEN and HEARTS

	INTERVENTIONS OR TOOLS	WHO-PEN	HERTS	COMMENTS
Leadership and governance	Assessment of needs and gaps	$\checkmark$	$\checkmark$	Same as WHO-PEN but expanded
Clinical Protocols and Tools	Clinical guidance Risk prediction	$\checkmark$	$\checkmark$	Same as WHO-PEN but simplified for improved use
Medical products and technology	Define core medicines and affordable technology	$\checkmark$	$\checkmark$	Same as WHO-PEN
Health information systems	Provide templates for collecting health information Devise a reliable system for monitoring, with appropriate indicators	V		Need for expanded system for longitudinal follow- up
Health workforce	Provide training materials to enhance knowledge and skills in CVD management		$\checkmark$	Need for robust training for health workers
Service delivery	Define the core set of interventions Provide robust implementation tools and support	$\checkmark$		Same as WHO-PEN but expanded



## Scope of HEARTS

The HEARTS technical package includes interventions in primary health care as the first step in improving CVD management in countries and as a part of the overall framework of CVD prevention and control. Although interventions at the population level and in the health system have a broader scope, the specific focus of the technical package is to ensure robust implementation and scaling-up of clinical preventive services in primary health care. It also provides the necessary structure to link to higher levels of care as well as to the community (Fig. 4). After successful implementation of the HEARTS package in primary health care, the next step would be to extend the package to interventions at district and referral levels.

#### Fig. 4. Sample service delivery model for CVD management using the HEARTS technical package



The service delivery model will depend on the country and the availability of trained personnel, medicines and technology at primary health care centres. The implementation plan in the technical package includes a detailed process for adaptation in countries, which allows for the inclusion of additional protocols. The barriers that hinder implementation in countries can be analysed with other tools, such as the World Heart Federation roadmaps (11), which can be used in conjunction with the HEARTS technical package.

#### **Target audience**

The HEARTS technical package was created for use by national and subnational programme managers to improve their CVD prevention and management programmes. It can also be used by physicians and workers at all levels of the health-care system where primary care is provided in the private and public sectors. The package is also relevant for academics and the donor and development community as a blueprint for CVD management programmes.

# Elements of HEARTS



#### HEALTHY LIFESTYLE

Counselling on tobacco cessation, diet, physical activity, alcohol use and self-care

. . . . . . . . . . . .



#### **EVIDENCE-BASED TREATMENT PROTOCOLS** Simple, standardized algorithms for clinical care



#### A ACCESS TO ESSENTIAL MEDICINES AND TECHNOLOGY

Access to core set of affordable medicines and basic technology



#### R RISK-BASED MANAGEMENT

Total cardiovascular risk assessment, treatment and referral



#### **I** TEAM CARE AND TASK-SHARING

Decentralized, community-based and patient-centred care



#### **S** SYSTEMS FOR MONITORING

Patient data collection and programme evaluation

NHÓM TRÁI CÂY



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### **Healthy lifestyle**

#### Counselling on tobacco cessation, diet, physical activity, alcohol use and self-care

#### **Evidence and rationale**

#### What is it?

Counselling on lifestyle changes, including tobacco cessation, dietary modification, avoiding harmful use of alcohol and increasing physical activity, involves systematic, targeted use of information and techniques to support individual behavioural change. The aim is to promote the necessary knowledge, motivation and skills. The intensity and frequency of lifestyle counselling depends on the overall CVD risk, with high-risk individuals requiring more rigorous interventions. Counselling can be delivered by trained providers in the primary care setting.

Self-care is the ability of individuals, families and communities to promote and maintain health, prevent disease and cope with illness and disability with or without the support of a health-care provider (12). It is based on strategies such as staying fit and healthy and avoiding hazards such as smoking, as well as elements of self-monitoring and self-management. Self-care strategies complement and optimize standard clinical care.

#### Why is it important?

Strategies to address multiple risk factors by lifestyle counselling and appropriate drug therapy are the mainstay of CVD prevention. Encouraging people at risk for CVD to avoid unhealthy activities such as smoking and harmful use of alcohol and to participate in healthy activities such as exercise and eating a healthy diet is a proven intervention for improving cardiovascular health and decreasing risk. Systematic reviews of high-intensity combined lifestyle counselling for people with CVD risk factors show reduced cholesterol, blood pressure, weight, glucose level and diabetes incidence after 12–24 months, although it is unclear whether counselling has long-term effects on CVD events and mortality in LMICs *(13-15)*.

Systematic lifestyle counselling is routinely underused as a standard management tool for high-risk individuals in many LMICs. Many health-care providers are not adequately trained to provide effective counselling, and their advice, when given, is usually limited to brief general comments such as "stop smoking", "eat better food" and "exercise more" and rarely includes specific recommendations or referral. For instance, despite the evidence for the effectiveness and cost-effectiveness of brief tobacco interventions, more than 50% of primary care providers, especially in LMICs, do not deliver these interventions routinely, citing lack of knowledge and skill in counselling about tobacco

and tobacco control as major barriers (16). WHO-PEN guidelines recommend intensive behavioural counselling for individuals at high risk for CVD and continuous lifestyle counselling for all adults as part of comprehensive NCD management in primary health care.

Self-care for CVD management is an important strategy to improve long-term adherence as compliance with recommended treatments and lifestyle changes is often poor. Education on self-care should include the provision of materials appropriate to the local context; use of group education can be cost effective for promoting self-care (8). Use of technologies such as mobile phones may improve access to education and adherence support services such as medication reminders.

#### Approach

The HEARTS technical package will facilitate lifestyle counselling and self-care by building on available resources. This will include incorporation of tobacco cessation advice and treatment of tobacco dependence, as contained in the MPOWER package, as a core function of the primary health care system (17). To ensure effective treatment of tobacco dependence, health-care workers will have to create a sustainable infrastructure to motivate attempts to quit smoking, ensure wider access for tobacco users who wish to quit and assure adequate resources for such support. Tools will be adapted to address harmful use of alcohol, and provide specific advice on healthy diets and appropriate physical activity in the country context and cultural norms; interpretation of what constitutes a "healthy diet" or "adequate physical activity" depends wholly on the local situation. The HEARTS approach will include:

- simplified protocols for lifestyle counselling as a core part of evidence-based protocols for CVD and diabetes management, including use of decision-support algorithms delivered by digital or mobile technology where available;
- prioritizing training of health-care providers, including non-physicians, in delivering effective, high-quality behaviour modification interventions, such as smoking cessation and nutrition counselling, using motivational interviewing techniques; and
- provision of appropriate, context-specific education materials to improve people's knowledge about CVD risk factors and complications, and to promote the importance of self-care and adherence.

#### How will it be done?

• Define lifestyle counselling as a part of the service delivery package, and build the capacity of the health-care provider team for simple, effective counselling.

- Provide resources to equip health-care providers for direct or referred comprehensive, effective counselling on tobacco cessation, healthy diets, physical activity, harmful use of alcohol and compliance with medication.
- Promote self-care, and use community health workers to support compliance outside the clinical setting.

#### Tools for healthy lifestyle interventions and self-care:

- WHO-PEN Protocol 2: Health education and counselling on healthy behaviour (Annex 1b);
- Toolkit for delivering the 5A's and 5R's brief tobacco interventions in primary care (18);
- Train primary health care providers to deliver tobacco cessation interventions (Annex 1c) (19);
- WHO modules for self-care (Annex 1d) (8).



Case study: Isfahan "healthy heart programme" in the Islamic Republic of Iran (20)

The objective of the Isfahan "healthy heart programme" was to assess the effectiveness of a comprehensive, integrated, community-based intervention on diet, physical activity and smoking in two Iranian communities. The trial was conducted in two intervention counties (Isfahan and Najaf-Abad) and a control area (Arak), with lifestyle interventions targeted at the urban and rural populations in the intervention counties but not in the control area. In each community, a random sample of adults was selected, and parameters such as food consumption, physical activity and smoking behaviour were assessed, scored and totalled to derive an overall lifestyle score. Scoring was repeated annually for four years in the intervention areas and for three years in the control area.

Multiple interventions were used, from population health education to specific interventions for high-risk individuals and CVD patients after hospital discharge. A dietary score (0-12) was assigned to participants where higher numbers indicated healthier diet choices as quantified by a food frequency questionnaire. After four years, significant differences were found in the mean dietary score (+2.1 points and -1.2 points) and in the percentage of people following a healthy diet (+14.9% and -2.0%) between the intervention and the control groups, showing improved diet choices by those who received the intervention. There was no statistically significant difference in smoking between the two groups. Overall, there was a significant improvement from baseline in the mean lifestyle scores in the intervention group as compared to the control group, even after controlling for age, sex and baseline values.

The authors concluded that community lifestyle intervention programmes can be effective in a developing country.



### **Evidence-based treatment protocols**

Simple, standardized algorithms for clinical care

#### **Evidence and rationale**

#### What is it?

Evidence-based treatment protocols are national or subnational protocols for the management of CVD developed through a collaborative, consultative process for use by health professionals at all levels. They should be clear and simple to follow and be integrated into national guidelines or recommendations for clinical management. They should be updated regularly as new evidence is obtained, and disseminated widely to ensure uptake and use (21).

#### Why is it important?

In many LMICs, there is a wide gap between evidence-based recommendations and current practice. Treatment of major CVD risk factors remains suboptimal and only a minority of patients who are treated reach their target levels for blood pressure, blood sugar and blood cholesterol. In other areas, overtreatment can occur with the use of non-evidence-based protocols. The aim of using standard treatment protocols is to improve the quality of clinical care, reduce clinical variability and simplify the treatment options, particularly in primary health care (22). Standard treatment protocols can be developed by preparing new national treatment guidelines or by adapting or adopting international guidelines such as the WHO-PEN. In a WHO survey of country capacity in 2015, 67% of countries reported having evidence-based national guidelines/protocols/ standards for the management of CVD; of these, however, only 53% of countries with guidelines reported their full implementation (Fig. 5) (23).





Source: World Health Organization 2016 (23).

When treatment guidelines are available, they must be translated into simple operational protocols and treatment flow charts or algorithms that are easy to access for primary health care providers. Many current guidelines for the diagnosis and management of CVD are complex and may be impractical to use in resource-constrained settings (24).

The use of simplified, standardized treatment protocols is important for scalingup CVD management, particularly in primary health care, as they are essential for decentralization of care, the involvement of non-physician health workers and defining a core set of medicines (25). Treatment algorithms could be integrated into electronic health systems, with provider prompts to guide care, or could be as simple as a poster or printed booklet at points of care.

#### Approach

The HEARTS technical package will include simple, standardized treatment protocols for CVD risk management, including integrated algorithms for secondary prevention and for the management of high blood pressure, high blood cholesterol and diabetes. Protocols for tobacco cessation, healthy lifestyle counselling, self-care and referral care will also be part of the overall package for CVD management (Annex 1).

The approach includes guidance for adapting protocols to the local context and using the appropriate protocols for managing individuals at high risk, including cardiovascular risk assessment, counselling and drug therapy, specified intervals for follow-up and re-evaluation and criteria for referral to higher levels of care.

The package promotes use of standardized management protocols for people on drug treatment for hypertension and diabetes to ensure appropriate titration and monitoring of medications in order to meet treatment targets.

#### How will it be done?

- Adapt simple, standard treatment protocols for use in primary health care.
- Support and ensure use of simple, standard protocols, and offer decision-support systems to providers.
- Monitor and evaluate the effectiveness of use of the protocols.

#### Tools for evidence-based protocols:

 WHO-PEN protocol 1: Protocol for prevention of heart attacks, strokes and kidney disease within integrated management of diabetes and hypertension (Annex 1a);

- WHO-PEN Protocol 2: Health education and counselling on healthy behaviour (Annex 1b);
- Algorithm for blood pressure management with drug therapy;
- Algorithm for diabetes management with drug therapy;
- Algorithms for the management and referral of acute presentations of chest pain or heart attacks, strokes and possible cardiac failure; and
- Algorithm for secondary prevention in people with prior CVD.



Case study: Effective use of treatment protocols in China and Nigeria (26)

A simple CVD risk management package for assessing and managing hypertension on the basis of CVD risk was evaluated in China and Nigeria. The package contained a simple protocol based on guideline recommendations and optimized for primary prevention in low-resource settings.

Two geographically distant regions in China and Nigeria were selected, and 10 pairs of primary care facilities in each region were randomly selected, matched and randomly assigned to either a control group, which received the usual care, or to an intervention group, with use of the CVD risk management package. Each facility enrolled 60 consecutive patients with hypertension. The intervention consisted of educating patients about risk factors at baseline and providing drug treatment for those at medium risk for a cardiovascular event, according to a standardized treatment algorithm. A change in systolic blood pressure between baseline and 12 months was the primary outcome measure.

A total of 2397 patients with baseline hypertension (1191 in 20 intervention facilities and 1206 in 20 control facilities) were enrolled. Both systolic and diastolic blood pressure and hypertension control rates were improved in those who received the intervention as compared with controls. Use of the package significantly increased the number of prescriptions of the recommended anti-hypertensive (hydrochlorothiazide).

The authors concluded that a simple intervention with standardized treatment for people at risk for CVD improved blood pressure control and prescription of anti-hypertensive drugs in selected primary care facilities in two resource-limited countries.



# Access to essential medicines and technology

Access to a core set of affordable medicines and basic technology

#### **Evidence and rationale**

#### What is it?

In order to scale up clinical CVD management in primary health care, there should be equitable access – measured as price, availability and affordability – to good quality essential medicines, diagnostics and basic technology for clinical management. All three aspects should be improved in order to implement CVD management in LMICs.

#### Why is it important?

Although most essential CVD medicines exist in generic form, their availability and affordability are poor in many LMICs, representing a significant barrier to access. Essential technologies (e.g. accurate devices for blood pressure measurement, risk-assessment charts, weighing scales, height measuring equipment, blood sugar and blood cholesterol measurement devices with strips, and urine strips for albumin assay) and medicines (e.g. aspirin, a statin, a thiazide diuretic, an angiotensin-converting enzyme inhibitor, a calcium-channel blocker, a beta-blocker, metformin and insulin) are frequently not found in public hospitals, health centres or community pharmacies. When medicines are available, they are either too expensive for most people, of low quality or questionable efficacy, or otherwise stocked in such small quantities that only a few



### Fig. 6. Percentages of countries where selected basic technologies are available for early detection, diagnosis and monitoring of CVD in public and private primary care facilities, by WHO region

AFR, African Region; AMR, Region of the Americas; EMR, Eastern Mediterranean Region; SEAR, South-East Asia Region; WPR, Western Pacific Region

Source: World Health Organization 2016 (23).

people can be treated for short periods. There are similar deficits in the availability of basic technologies for diagnosis and treatment (Fig. 6) (23).

A survey of 40 countries in 2011 indicated that low-cost medication for the treatment of NCDs in LMICs was up to 20% less accessible than medicines for infectious disease and was often sold at a significantly marked-up price or in brand name form only (27). In settings with few medical insurance schemes, this increases out-of-pocket expenditure or makes these basic life-saving drugs out of reach. In rural India, the cost of a statin or an angiotensin-converting enzyme inhibitor represents up to 50% and 20%, respectively, of a household's median monthly income (28). Other factors that perpetuate stockouts and poor availability of medicines are the absence of data to forecast medication needs and poor procurement capacity in many LMICs. The challenges in ensuring access to essential medicines require solutions at different levels.

#### **Fixed-dose combinations**

A fixed-dose combination is a drug that includes two or more active drug ingredients combined in a single dosage form. They are widely used in the treatment of many infectious diseases, including antiretroviral treatment for patients with HIV. Fixed-dose combinations have transformed the delivery of care by improving access, affordability and patient adherence to essential treatment. Fixed-dose combinations for CVD (the "polypill") have been proposed for inclusion in the Model List of Essential Medicines. Use of these combinations for secondary prevention and primary prevention in high-risk individuals CVD could close gaps in treatment of these conditions by reducing drug costs, improving adherence and simplifying the drug regimen for patients who take them and health-care workers who prescribe them (29). The HEARTS technical package advocates use of initial combination anti-hypertensive treatment for stage II hypertension (systolic blood pressure ≥ 160/100 mmHg).

#### Approach

The HEARTS technical package addresses the need to improve access to essential medicines and basic technology:

- It promotes the use of simplified treatment protocols with a defined list of core medicines and technology for managing key CVD risk factors. The core medicines include the most efficacious, safe, low-cost drugs selected on the basis of current evidence-based guidelines.
- It will improve procurement and distribution by the use of existing mechanisms for other diseases. Improving procurement and distribution allows governments to set policies and strategies to promote access, avoid breaks in the supply chain and assure the quality of essential medication.

#### How will it be done?

- A core set of medicines and basic technology is defined; it will be extended by the inclusion of fixed-dose combinations where available.
- The continuous availability of high-quality essential medicines and basic technology will be assured for primary health care settings.

#### Tools for improving access to essential medicines and technology:

- core list of essential medicines and technology for CVD and diabetes management in primary health care (Annex 2);
- rapid, mobile-based drug survey tool;
- handbook for supply management; and
- handbook on access to essential medicines and technology for NCDs.



Case study: Pan American Health Organization (PAHO) strategic fund (30)

PAHO, through its strategic fund, procures high-quality medicines at low cost in Latin America and the Carribean. The fund was started to improve access to vaccines and expanded to improve access to antimalarials, antiretrovirals and, in 2013, drugs for NCDs. The fund, therefore, now covers the full spectrum of medicines for communicable diseases and NCDs and is available to all PAHO Member States. As countries purchase through the strategic fund, their purchasing power increases, resulting in lower product prices for participating countries. The CVD medicines comprise 13 anti-hypertensives, 1 lipid-lowering agent and 2 anti-thrombotics.

All suppliers of medicines available through the strategic fund are prequalified by WHO and are selected on the basis of the quality of their products, the proposed prices and performance history. The fund negotiates with international suppliers to obtain low prices and all products offered meet WHO quality standards. The fund also offers technical support to participating countries in supply management and procurement planning, applying quality assurance norms in procurement and facilitating coordination between suppliers and countries. It also offers Member States interest-free loans to finance procurement of essential medicines.

Currently, 27 Member States participate in the fund. In 2015, Member States used the fund to make over 400 requests to purchase over US\$ 70 million worth of drugs. The PAHO strategic fund is a model for similar strategies to improve access to CVD medicines on a regional basis, especially for more expensive medications that are not available as generics. Other aspects of the programme, including the provision of technical assistance, procurement support and credit facilities, are also applicable.


# **Risk-based management**

Total cardiovascular risk assessment, treatment and referral

### **Evidence and rationale**

### What is it?

CVD risk stratification consists of the categorization and management of people according to their likelihood or chance for a cardiovascular event (heart attack or stroke). The level of risk is determined with simple risk-scoring tools and calculated as the combined effect of multiple risk factors, including age, gender, smoking status, blood pressure and total cholesterol or body mass index. It is expressed as the probability of developing CVD over a defined period such as 10 years. Decisions about whether to initiate preventive interventions and treatment intensity are guided by the level of risk. Individuals at higher risk for CVD events require more intensive management. Conversely, low-risk individuals who might not benefit sufficiently from such interventions are spared the associated harms and cost of overtreatment.

### Why is it important?

The likelihood of a cardiovascular event is often determined by the confluence of multiple risk factors. Risk factors tend to cluster in individuals; the combined effect is synergistic and increases the risk for events. Although CVD risk can be assessed qualitatively, that approach is often inaccurate and error-prone, hence the development of quantitative risk prediction tools for use by health providers to estimate the risk of an individual for CVD (*31*). Several clinical trials have shown that modification of CVD risk factors, including high blood cholesterol and blood pressure, reduces the number of clinical events and premature deaths in people with established CVD and in those at high or intermediate risk for CVD due to one or more factors (*32–35*).

Comprehensive risk assessment in adults with no known CVD using simple risk-scoring tools can help identify those at high risk and initiate early preventive interventions (36). Major global guidelines promote the use of multivariable risk scores to guide treatment decisions in primary prevention (37,38). A hybrid approach, involving treatment based on absolute risk and treatment of individuals with high blood pressure ( $\geq$  160/90 mmHg) or high blood cholesterol (total cholesterol  $\geq$  8 mmol/dL), is the basis for the WHO guidelines.

This approach is especially important in LMICs, where many primary care facilities do not offer CVD risk assessment and most patients remain unaware of their underlying cardiovascular risk (Fig. 7). In the global context of limited resources for CVD management, this total risk strategy is also cost effective (*39*). The threshold for drug treatment of high-risk individuals can be determined on the basis of the economic and health system realities in each country. Some countries might place a threshold of 30% for a 10-year risk for CVD, while countries with more resources might consider a threshold of 20% or 10%, depending on their circumstances.

## Fig. 7. Reported percentages of primary health care facilities offering CVD risk stratification for the management of patients at high risk for heart attack and stroke, by WHO region



AFR, African Region; AMR, Region of the Americas; EMR, Eastern Mediterranean Region; SEAR, South-East Asia Region; WPR, Western Pacific Region Source: World Health Organization 2016 (23).

### **Secondary prevention**

Risk-based treatment also covers individuals with a history of CVD (secondary prevention), who often experience recurrent events but do not receive recommended drugs such as aspirin, statins, beta-blockers and angiotensin-converting enzyme inhibitors. Data from the Prospective Urban and Rural Epidemiology (PURE) study showed significant gaps in coverage in the study population where 50–75% of people with prior CVD, mostly in LMICs, received none of the recommended medicines for secondary prevention (3). In the risk-based management approach, individuals with prior CVD are immediately classified in the highest risk category and managed accordingly with medication and intensive lifestyle counselling (Fig. 8).

### Fig. 8. Flow chart of CVD risk assessment and management



### Approach

Updated CVD risk prediction charts will be available for each country, based on their specific country data on risk factors and cardiovascular mortality. The updated charts will be available on paper but also electronically and in mobile applications, with links to simplified management algorithms and decision support for health workers.

### How will it be done?

- Assess the appropriate target population presenting to primary health care facilities by country-specific total CVD risk estimation to categorize their risk for CVDs.
- Define appropriate thresholds for treatment and referral.
- Simplify CVD risk assessment by offering non-laboratory-based tools and the use of electronic and mobile applications.

### Tools for risk-based management:

 WHO/International Society of Hypertension (ISH) risk prediction charts for WHO regions to be used for CVD risk assessment in individuals with no manifest CVD (Annex 3). The charts can be used when laboratory values, such as blood cholesterol levels, are available. Individuals with established coronary heart disease, cerebrovascular disease, peripheral vascular disease, diabetes or chronic kidney disease are considered to be at high risk for events and require intensive lifestyle interventions and appropriate drug therapy. Risk stratification with risk charts is not required for deciding treatment for this population. Other validated risk scoring methods can be used based on country preference.

• WHO country-specific charts are in development, with electronic and mobilebased applications for CVD risk assessment. Versions of the chart where body mass index is used instead of blood cholesterol will be available.



Case study: Total CVD risk management in Seychelles (40)

In Seychelles, a small island country in the WHO African Region, nearly 40% of all deaths are attributable to CVD; hence, cost-effective prevention strategies are important. A study was conducted to compare the cost-effectiveness of single risk-factor management (treating individuals with blood pressure  $\geq$  140/90 mmHg and/ or total blood cholesterol  $\geq$  6.2 mmol/L) with that of management based on total CVD risk (treating individuals with a total CVD risk  $\geq$  10% or  $\geq$  20%).

The WHO/ISH cardiovascular risk prediction chart for the African Region was used to estimate the 10-year risk for a fatal or non-fatal cardiovascular event among people aged 40-64 years who participated in a nationwide health survey in 2004. The data were used to compare single risk-factor management with total risk management in terms of the number of people who required treatment to avert one cardiovascular event and the number of events potentially averted over 10 years.

With single risk-factor management, 60% of adults would require treatment and 157 cardiovascular events would be averted per 100 000 population per year as compared with 5% of adults treated and 92 events averted per 100 000 population with total CVD risk management. Management based on a high total CVD risk optimized the balance between the number requiring treatment and the number of events averted.

The authors concluded that total CVD risk management is more cost effective than single risk-factor management, especially in LMICs.





# **Team care and task-sharing**

Decentralized, community-based and patient-centred care

### **Evidence and rationale**

### What is it?

An adequately trained local workforce with the capacity to initiate and sustain CVD prevention and management programmes is a critical component of care delivery. Many low-resource settings have a shortage of physicians and health workers (41,42). A team-based, task-sharing approach is necessary to strengthen and expand the workforce. Task-sharing is defined as the allotment of tasks usually performed by highly trained health-care workers (doctors and nurses) to less specialized health workers, who often have less education and training (43,44). Even in low-resource settings, patients can effectively be assessed for CVD risk and managed in primary care facilities by non-physician health workers (26).

### Why is it important?

Rapid improvement in access to health services can be achieved by a team or task-sharing approach (Fig. 9). Training non-physician health workers to perform tasks traditionally undertaken by doctors allows expansion of care in settings where there is a shortage of doctors or in other settings to expand capacity. These health-care workers can be retrained and become effective in providing primary care for CVD risk factors such as hypertension and diabetes, to a similar standard as the care provided by physicians (45). This frees doctors to treat more complex cases and improved efficiency can generate cost savings in the health system. This is a radical departure from inefficient models of care that depend on cardiologists and other specialists; a multidisciplinary care team with defined competence and scope of work can be much more efficient.

### Fig. 9. Task-sharing to expand the pool of human resources for health



Task-sharing is also cost effective (46). LMICs can encourage self-care and ensure better coverage of essential interventions by training primary health care staff in early detection using CVD risk assessment and encouraging community engagement.

Task-sharing is effective, however, only in a system with adequate checks and balances for both health workers and patients. Appropriate health legislation is required, and the health system should provide simplified treatment algorithms, a core set of medicines for treatment and the support of physicians and practitioners at a higher level of care to ensure continuous training, supervision and reception of referrals of complex cases. Quality improvement measures should also be present, i.e. a structured approach to analysing performance and systematic ways to improve it.

### Approach

The HEARTS technical package will support team care and task-sharing by:

 training health-care providers, including non-physician health-care workers, in using CVD risk management protocols so they can appropriately identify, treat and refer high-risk patients and complex cases, collect clinical information and maintain simple treatment registers;

- ensuring definition of appropriate services at each level of care and agreement on the roles for each type of health worker during preparation or adaptation of guidelines and protocols; and
- building on WHO normative work in training in and use of task-sharing approaches and incorporating existing tools.

### How will it be done?

- Define services at different levels of the health care system, and form teams to provide the full range of services required.
- Provide incentives for task-sharing, with supportive supervision and skill-building.
- Support and sustain community links.

### Tools for team care and task-sharing:

Standardized training materials will be prepared for use in various settings after translation and adaptation to each country. The objectives of the tools will be to transfer the knowledge and skills necessary to deliver the protocols for CVD management and lifestyle counselling and to use the recording and reporting procedures for information management.

- Training package to develop key competencies, including:
  - delivery of essential CVD and diabetes management interventions to diagnose, treat and appropriately refer patients;
  - interpretation of the results of measurements of blood pressure, blood cholesterol (if available) and blood sugar;
  - appropriate use of the CVD risk assessment charts to triage patients and decide on treatment and follow-up according to risk;
  - use of the clinical data system to collect and report essential data for clinical care, monitoring and evaluation;
  - delivery of appropriate preventive health interventions, including individual lifestyle counselling, health education messages and self-care strategies; and adherence to drug therapy and counselling;
- Human resources for health toolkit (47)



China and India face similar challenges and opportunities in CVD prevention and control. Both are growing economies, with limited resources and capacity particularly in rural areas, large population bases and increasing access to mobile phones. Health systems in the two settings, relied in the past on relatively few, overburdened specialists for implementing CVD prevention strategies; use of human resources was, therefore, unsustainable.

In a randomized trial in 2011, a simplified CVD management programme (SimCard) delivered by community health workers was introduced in 47 villages in the two countries, and 2086 high-risk individuals were recruited. The intervention consisted of two medicines (blood pressure-lowering agents and aspirin) and two lifestyle interventions (smoking cessation and salt reduction), with an electronic decision-support system. Villages were randomly assigned to intervention or control, with stratification by country. Community health workers were trained before the intervention to screen patients, measure blood pressure, provide lifestyle counselling and, when appropriate, prescribe one or both medicines. The health workers received refresher training every three to four months during the intervention and made monthly follow-up visits to the high-risk participants in the study.

At the end of the trial, the intervention group had a statistically significant increase in use of anti-hypertensives and aspirin and lowered systolic blood pressure. The results suggest that a simplified CVD management intervention for high-risk individuals can be successfully delivered by community health workers.

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# **Systems for monitoring**

### Patient data collection and programme evaluation

### **Evidence and rationale**

### What is it?

Basic demographic and clinical data are registered for follow-up care, to track adherence and trends in the use of health services and to monitor and evaluate programmes (49). The data include basic longitudinal patient clinical records, clinical registers to monitor treatment patterns and outcomes and cohorts to collate clinical information on all patients at high risk for CVD or with specific risk factors in a particular catchment area over time. Monitoring systems can be maintained as paper or electronic records, depending on capacity.

### Why is it important?

The existing data systems for CVD management in many LMICs face several challenges. Similar to the underlying care delivery systems, monitoring of patients and programmes, when it exists, is often rudimentary and used for unstructured, episodic care. The data systems are often not robust enough to manage the longitudinal data required for the care of patients with chronic disease, with a lack of standards, tools and resources for monitoring. A well-functioning data system is the backbone of effective case management for CVD and other chronic diseases and this has been successfully demonstrated in tuberculosis and HIV programmes in LMICs (50). A reliable monitoring system is critical for improving patient care and service delivery, including forecasting procurement of drugs and commodities, human resources, quality improvement and logistics (51).

Several approaches can be used to strengthen a health management information system, starting at the facility and moving up to the subnational or national level. Using the example of tuberculosis control programmes, the development of core standard indicators (both clinical and process), data collection forms and data systems is an important first step (Fig. 10).





Data are then collected at the facility level from patient clinical records that can be collated into clinical registries and aggregated into national and subnational level cohorts. Cohort monitoring is a useful way of assessing whether interventions are effective and for tracking progress. Electronic health record systems allow realtime data collection from a linked electronic health record for easy monitoring of individual and cohort outcomes.

Timely, complete recording and transfer of data can be achieved only if personnel are adequately trained. Training in collecting, analysing, interpreting and using highquality data should, therefore, be part of training for providers in CVD management. A functioning health management information system can streamline patient care and decrease the workload of providers. The flow of information is depicted in Fig. 11.

### Fig. 11. Flow of information with data collection and aggregation tools



HEARTS: Technical package for cardiovascular disease management in primary health care

### Approach

In the HEARTS technical package, systems for patient monitoring, registration and cohort monitoring will be aligned with ongoing initiatives to standardize health management information systems in primary health care. It will include a toolkit that will be developed collaboratively to facilitate development of new systems or integration of existing ones.

Countries with limited resources may initially use clinical records, registers and summary indicators on paper, although use of electronic systems will be encouraged and the appropriate modules developed. Several initiatives are under way to standardize health management information systems in countries, including the Health Data Collaborative (52). Monitoring systems that are components of the HEARTS package will be aligned with existing country initiatives.

### How will it be done?

- Develop or adapt locally appropriate, systematic monitoring of patients using paper or electronic systems.
- Use appropriate, standardized indicators to assess programme performance and coverage.
- Monitor and report outcomes to facilities and at subnational and national levels.

### Tools for monitoring systems:

The toolkit of the HEARTS technical package will support the following components of health management information systems in facilities with:

- preparation or adaptation of an appropriate minimum set of core clinical indicators and process indicators (Annex 4);
- routine data on service delivery using client screening forms, registers and monthly summary forms; and
- aggregation of subnational data in an electronic database to allow analysis, visualization and comparison of monthly and quarterly performance, with annual reporting.



Case study: Cohort monitoring for hypertension among Palestinian refugees in Jordan (53)

The United Nations Relief and Works Agency for Palestinian Refugees in the Near East (UNRWA) has a long history of providing education, health and social services for 5 million Palestinian refugees. An important component of the health-care services is diagnosis and care of NCDs, including hypertension and diabetes.

In 2011, 6 of 24 primary health-care centres run by UNRWA for Palestinian refugees in Jordan were enrolled in a study of cohort monitoring for hypertension treatment. The aim of the study was to determine whether the data obtained could improve the quality of care and case management. The Directly Observed Treatment, Short Course (DOTS) system for monitoring tuberculosis was adapted to monitor patients with hypertension using an electronic record system.

Of the 4130 patients registered with hypertension in the e-health system by the first quarter of 2012, 76% remained in care at the end of the quarter, 21% were lost to follow-up and the remainder had died or been transferred. The cohort outcome analysis showed several deficiencies in clinical performance, including blood pressure measurement and testing of fasting blood glucose. It also showed that 8–15% of the cohort had serious complications, such as heart attacks and strokes.

The cohort monitoring system was found to be useful for planning and managing CVD and other public health services, such as rational forecasting of drugs, technology and consumables, including blood pressure machines, treatment cards and testing strips.

# **Approach to implementation**

Careful planning and evaluation are required to ensure that the HEARTS technical package has the desired impact in primary health care. Partners will compile a standard set of technical resources, including those available on platforms at WHO, the Centers for Disease Control and Prevention (CDC) in the United States, the World Heart Federation and other institutions. The HEARTS toolkit will include modules to support each element of HEARTS and a manual providing guidance on adaptation and use of the tools.

### **Toolkit for the HEARTS package**

Elements of the HEARTS package will be implemented with the toolkit outlined in Fig. 12. The toolkit will provide an operational framework and the modules necessary to ensure that the services that are delivered are integrated, efficient and of high quality.





### Implementation manual

An implementation manual will be prepared for national and district programme managers, which will provide tools to:

- support planning and implementation of HEARTS by stakeholders;
- assess the capacity of and gaps in primary care health infrastructure and facilities;
- design communication messages for advocacy and community engagement;
- adapt the health information system to monitor and evaluate use of HEARTS and align it with the existing system;
- adapt training materials for the health workforce;
- monitor and evaluate implementation at a demonstration site;
- prepare a district plan and a national extension plan; and
- organize systematic supervision and evaluation of implementation.

The initiative will be pilot-tested in countries with these technical tools. Systematic analysis and documentation of the findings in the pilot countries will form the basis for revision of the technical package and identify scalable solutions. The equity of any impacts will be monitored and, in particular, WHO will support pilot countries to assess programme effectiveness by sex and for different socioeconomic groups.

### Logic model of the HEARTS technical package

The HEARTS logic model summarizes the links among the elements of the package, the strategies required to implement the elements, the expected outcomes and the resources or inputs necessary to achieve short-, intermediate- and long-term outcomes (Fig. 13). It describes the processes for reaching the outcomes and situates them in the context in which the technical package will be implemented.

The logic model provides a concise programme overview and a reference point for planning, evaluating and implementing the HEARTS technical package.

OUTCOMES	<ul> <li>SHORT-TERM OUTCOMES</li> <li>Establishment of a care system/ improved care delivery</li> <li>Increased numbers of patients seen for CVD management Increased assessment of cardiovascular risk</li> <li>Increased prescription of CVD medications</li> <li>Increased public awareness</li> <li>Increased awareness around CVD risk factors</li> </ul>	<ul> <li>Improved CVD risk factor management (hypertension control, cholesterol management, diabetes management, appropriate referrals)</li> <li>Imcreased access to essential medication and technology increased smoking assessment and treatment</li> <li>Decreased smoking prevalence</li> <li>Decreased smoking prevalence</li> <li>Development of clinical quality measures and registry system</li> <li>T0% reduction in premature CVD mortality in populations covered under the initiative</li> <li>Standardized modules</li> <li>Standardized modules and hypertension control</li> <li>Standardized modules</li> <li>Standardized modules and hypertension control</li> </ul>	<
OUTPUTS	<ul> <li>Increased number of providers offering patient education and counselling increased community education campaigns</li> <li>Increased uptake and use of standardized treatment and management protocol</li> <li>Increased availability of core medications and reductions of stockouts in facilities</li> </ul>	<ul> <li>Increased affordability of core medications</li> <li>Increased number of eligible patients on appropriate drug treatments</li> <li>Increased medication adherence using fixed-dose combination</li> <li>Increased use of risk assessment tool to guide clinical decision- making</li> <li>Increased use of non-physician health workers and community</li> <li>Increased use of non-physician health workers and community</li> <li>Increased use of non-physician health workers</li> <li>Increased use of non-physician hospitals</li> <li>Increased data use of clinical information system for patient monitoring increased data use for clinical information</li> </ul>	AND STROKE
	<ul> <li>RISK STRATIFICATION</li> <li>Assess people using total CVD risk estimation to categorize their risk status using blood pressure, diabetes or other parameters as entry point</li> <li>Define appropriate thresholds for treatment and referral</li> <li>Develop teams to provide the full</li> </ul>	<ul> <li>range of services Incentivize tasksharing with supportive supervision and skill- building</li> <li>Support and sustain community linkages</li> <li>Develop or adapt locally appropriate systematic monitoring of patients</li> <li>Use a set of appropriate and standardized indicators to assess the programme performance and coverage</li> <li>Monitor and report treatment outcomes</li> </ul>	RESS AND REDUCE HEART ATTACKS AND STROKE
HEARTS STRATEGY	<ul> <li>HEALTHY LIFESTYLES</li> <li>Offer counselling on tobacco cessation, healthy diet and physical activity and adherence to medications by health-care providers</li> <li>Promote self-care through educating patients and care givers</li> <li>EVIDENCE BASED TREATMENT</li> </ul>	<ul> <li>Promotion of national guidelines for CVD management</li> <li>Use of standard clinical protocols for CVD risk assessment and management, hypertension and diabetes management</li> <li>Define a core set of medications and technology</li> <li>Ensure availability, with adequate procurement and distributions leverage pooled procurement for CVD medications</li> </ul>	ASSESS, ADDRE
INPUTS	<ul> <li>PUBLIC SECTOR PARTNERS</li> <li>National Governments</li> <li>National Agencies</li> <li>Ministry of Haalth</li> <li>Ministry of Finance</li> <li>PRIVATE SECTOR PARTNERS</li> <li>Clinicians in private sector</li> <li>National professional</li> <li>organizations</li> <li>Public health practitioners</li> </ul>	<ul> <li>Nongovernmental organizations</li> <li>Foundations</li> <li>Resources</li> <li>National governments</li> <li>WHO regional and country offices</li> <li>CDC</li> <li>Other financial and human resources</li> </ul>	≺

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### Annex 1a. Protocol for prevention of heart attacks, strokes and kidney disease within integrated management of diabetes and hypertension (WHO-PEN protocol 1)

The protocol is for assessment and management of cardiovascular risk using hypertension, diabetes mellitus (DM) and tobacco use as entry points.

It could be used for routine management of hypertension and DM and for screening, targeting the following categories of people:

- age > 40 years
- smokers
- waist circumference (  $\geq$  90 cm in women;  $\geq$  100 cm in men)
- known hypertension
- known DM
- history of premature CVD in first degree relatives
- history of DM or kidney disease in first degree relatives

### FOLLOW INSTRUCTIONS GIVEN IN ACTION 1 TO ACTION 4, STEP BY STEP.

### ACTION 1. ASK ABOUT:

- Diagnosed heart disease, stroke, TIA, DM, kidney disease
- Angina, breathlessness on exertion and lying flat, numbness or weakness of limbs, loss of weight, increased thirst, polyuria, puffiness of face, swelling of feet, passing blood in urine etc
- Medicines that the patient is taking
- Current tobacco use (yes/no) (answer yes if tobacco use during the last 12 months)

### ACTION 2. ASSESS (PHYSICAL EXAM AND BLOOD AND URINE TESTS):

Waist circumference

FIRST VISIT

- Measure blood pressure, look for pitting oedema
- Palpate apex beat for heaving and displacement
- Auscultate heart (rhythm and murmurs)
- Auscultate lungs (bilateral basal crepitations)
- Examine abdomen (tender liver)
- In DM patients examine feet; sensations, pulses, and ulcers

### ACTION 3. ESTIMATE CARDIOVASCULAR RISK (IN THOSE NOT REFERRED):

- Use the WHO/ISH risk charts relevant to the WHO subregion
- Use age, gender, smoking status, systolic blood pressure, DM (and plasma cholesterol if available)
- If age 50-59 years select age group box 50, if 60-69 years select age group box 60 etc., for people age < 40 years select age group box 40
- If cholesterol assay cannot be done use the mean cholesterol level of the population or a value of 5.2 mmol/l to calculate the cardiovascular risk)

#### ACTION 4: REFERRAL CRITERIA FOR ALL VISITS:

- BP >200/>120 mm Hg (urgent referral)
- BP  $\geq$ 140 or  $\geq$  90 mmHg in people < 40 yrs (to exclude secondary hypertension)
- Known heart disease, stroke, transient ischemic attack, DM, kidney disease (for assessment, if this has not been done)
- New chest pain or change in severity of angina or symptoms of transient ischemic attack or stroke
- Target organ damage (e.g. angina, claudication, heaving apex, cardiac failure)
- Cardiac murmurs
- Raised BP ≥140/90 ( in DM above 130/ 80mmHq) while on treatment with 2 or 3 agents

Newly diagnosed DM with urine ketones 2+ or in

Any proteinuria

- lean persons of <30 years
- Total cholesterol >8mmol/l •
- DM with poor control despite maximal metformin with or without sulphonylurea
- DM with severe infection and/or foot ulcers
- DM with recent deterioration of vision or no eye exam in 2 years
- High cardiovascular risk

•

protein

Total cholesterol

- Alcohol consumption (yes/no) (if `Yes`, • frequency and amount)
- Occupation (sedentary or active)
- Engaged in more than 30 minutes of physical activity at least 5 days a week (yes/no)
- . Family history of premature heart disease or stroke in first degree relatives

Urine ketones (in newly diagnosed DM) and

Fasting or random blood sugar (diabetes=

(Point of care devices can be used for testing blood

If the person is already on treatment, use

is available to assess and record the

using current levels of risk factors)

obesity, raised triglyceride levels

pretreatment levels of risk factors (if information

pretreatment risk. Also assess the current risk

Risk charts underestimate the risk in those with

family history of premature vascular disease,

sugar if laboratory facilities are not available)

fasting blood sugar≥7 mmol/l (126 mq/dl)) or random blood sugar  $\geq$ 11.1 mmol/l (200 mg/dl))

	AC	n 5. Counsel all and treat as shown below	
	Risk < 20%	g	Add
	Risk 20 to <30%	Counsel on diet, physical activity, smoking cessation and avoiding harmful use of alcohol Persistent BP ≥ 140/90 mm Hg consider drugs (see below ** Antihypertensive medications) Follow-up every 3-6 months	
	Risk > 30%	<ul> <li>Counsel on diet, physical activity, smoking cessation and avoiding harmful use of alcohol</li> <li>Persistent BP ≥ 130/80 consider drugs (see below ** Antihypertensive medications)</li> <li>Give a statin</li> <li>Follow-up every 3 months, if there is no reduction in cardiovascular risk after six months of follow up refer to next level</li> </ul>	•
FIRST VISIT	actice points	<ul> <li>Consider drug treatment for following categories</li> <li>All patients with established DM and cardiovascular disease (coronary heart disease, myocardial infarction, transient ischaemic attacks, cerebrovascular disease or peripheral vascular disease), renal disease. If stable, should continue the treatment already prescribed and be considered as with risk &gt;30%</li> <li>People with albuminuria, retinopathy, left ventricular hypertrophy</li> <li>All individuals with persistent raised BP ≥ 160/100 mmHg; antihypertensive treatment</li> <li>All individuals with total cholesterol at or above 8 mmol/l (320 mg/dl); lifestyle advice and statins</li> </ul>	
	Important practice points	<ul> <li>* Antihypertensive medications</li> <li>If under 55 years low dose of a thiazide diuretic and/ or angiotensin converting enzyme inhibitor</li> <li>If over 55 years calcium channel blocker and/or low dose of a thiazide diuretic</li> <li>If intolerant to angiotensin converting enzyme inhibitor or for women in child bearing age consider a beta blocker</li> <li>Thiazide diuretics and/or long-acting calcium channel blockers are more appropriate as initial treatment for certain ethnic groups. Medications for compelling indications should be prescribed, regardless of race/ ethnicity</li> <li>Test serum creatinine and potassium before prescribing an angiotensin converting enzyme inhibitor</li> </ul>	

ACTION 5. COUNSEL ALL AND TREAT AS SHOWN BELOW

### Additional actions for individuals with DM:

- Give an antihypertensive for those with BP ≥ 130/80 mmHg
- Give a statin to all with type 2 DM aged ≥ 40 years
- Give Metformin for type 2 DM if not controlled by diet only (FBS>7mmol/I), and if there is no renal insufficiency, liver disease or hypoxia.
- Titrate metformin to target glucose value
- Give a sulfonylurea to patients who have contraindications to metformin or if metformin does not improve glycaemic control.
- Give advise on foot hygiene, nail cutting, treatment of calluses, appropriate footwear and assess feet at risk of ulcers using simple methods (inspection, pin-prick sensation)
- Angiotensin converting enzyme inhibitors and/or low-dose thiazides are recommended as first-line treatment of hypertension. Beta blockers are not recommended for initial management but can be used if thiazides or angiotensin converting enzyme inhibitors are contraindicated
- Follow up every 3 months

ADVICE TO PATIENTS AND FAMILY					
or					
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1					

References:

Prevention and control of noncommunicable diseases; Guidelines for primary health care, World Health Organization, 2012 Scaling up action against noncommunicable diseases. How much will it cost?, World Health Organization, 2011 Prevention of cardiovascular diseases; Pocket guidelines for assessment and management of cardiovascular risk, World Health Organization, 2008

Source: World Health Organization 2010 (8).

# Annex 1b. Health education and counselling on healthy behaviour (WHO-PEN protocol 2)\*

### **EDUCATE YOUR PATIENT TO:**

- Take regular physical activity
- Eat a "heart healthy" diet
- Stop tobacco and avoid harmful use of alcohol
- Attend regular medical follow-up

### TAKE REGULAR PHYSICAL ACTIVITY:

- Progressively increase physical activity to moderate levels (such as brisk walking); at least 150 minutes per week
- Control body weight and avoid overweight by reducing high calorie food and taking adequate physical activity

### EAT A HEART HEALTHY DIET:

Salt (sodium chloride)

- Restrict to less than 5 grams (1 teaspoon) per day
- Reduce salt when cooking, limit processed and fast foods

Fruits and vegetables

- 5 servings (400-500 grams) of fruits and vegetable per day
- 1 serving is equivalent to 1 orange, apple, mango, banana or 3 tablespoons of cooked vegetables

### Fatty food

- Limit fatty meat, dairy fat and cooking oil (less than two tablespoons per day)
- Replace palm and coconut oil with olive, soya, corn, rapeseed or safflower oil
- Replace other meat with chicken (without skin)

\*Updates pending

### STOP TOBACCO AND AVOID HARMFUL USE OF ALCOHOL:

- Encourage all non-smokers not to start smoking
- Strongly advise all smokers to stop smoking and support them in their efforts
- Individuals who use other forms of tobacco should be advised to quit
- Alcohol abstinence should be reinforced.\*
- People should not be advised to start taking alcohol for health reasons
- Advise patients not to use alcohol when additional risks are present, such as:
  - driving or operating machinery
  - pregnant or breast feeding
  - taking medications that interact with alcohol
  - having medical conditions made worse by alcohol
  - having difficulties in controlling drinking

### ADHERENCE TO TREATMENT:

- If the patient is prescribed a medicine/s:
  - teach the patient how to take it at home:
  - explain the difference between medicines for long- term control (e.g. blood pressure) and medicines for quick relief (e.g. for wheezing)
  - tell the patient the reason for prescribing the medicine/s
- Show the patient the appropriate dose
- Explain how many times a day to take the medicine
- Label and package the tablets
- Check the patient's understanding before the patient leaves the health centre
- Explain the importance of:
  - keeping an adequate supply of the medications
  - the need to take the medicines regularly as advised even if there are no symptoms

\*The recommendations in this protocol do not necessarily represent the position of the United States Centers for Disease Control and Prevention.

### Annex 1c. Tobacco cessation counselling protocol



\* Ideally second follow-up visit is recommended within the same month and every month thereafter for 4 months and evaluation after 1 year. If not feasible, reinforce counseling whenever the patient is seen for blood pressure monitoring.

Source: World Health Organization 2010 (8).

# Annex 1d. Self-care among patients with CVD or diabetes (WHO-PEN protocol 5)

### WHEN COULD THIS PROTOCOL BE USED?

All patients with NCDs perform some level of self-care. Health workers can work to strengthen self-care strategies in these patients by following this Protocol to implement the recommendations.

Counselling patients on self-care could be integrated into existing care structures.

All interactions with patients can be seen as opportunities to understand and improve the self-care strategies of patients.

	•	Using the Recommendations below, identify opportunities to improve self-care.
FIRST VISIT	•	Provide written or diagrammatical educational materials, and training in self-care, appropriate to the patient's needs, preferences and capacity.
	•	For self-care recommendations that require an action plan, agree on and provide a written or diagrammatical action plan.
ര		
FOLLOWING VISITS	•	Check the patient's progress.
	•	If necessary and the patient wishes it, repeat the steps from the first visit.
요		

### **RECOMMENDATIONS FOR ALL PATIENTS**

### Adherence

Strategies to improve adherence should form part of self-care for NCDs. Promotion of self-care in NCDs should take into account patients' beliefs and concerns about medicines, and their effects on adherence.

No single strategy to improve overall adherence is recommended over another. Health workers should use their skills, resources, and patient preferences to devise plans to improve adherence.

### Education

Group education programmes, rather than individual education may offer a cost effective strategy to deliver education in LMIC.

### CONDITION-SPECIFIC RECOMMENDATIONS

### Cardiovascular diseases

### **Raised blood pressure**

• Self-measurement to monitor blood pressure is recommended for the management of hypertension in appropriate patients where the affordability of the technology has been established.

### **Heart failure**

• Appropriate patients could benefit from being educated on the benefits of cardiac rehabilitation, and can be encouraged to undertake rehabilitation exercise in the home setting.

### **Need for anticoagulation**

• Self-monitoring of blood coagulation and self-adjustment of dosage in patients receiving oral anticoagulation agents is recommended if affordable and according to an agreed action plan with a health professional.

### **Diabetes**

### Diabetes Type 1 and 2

• People with type 1 and type 2 diabetes on insulin should be offered self-monitoring of blood glucose based on individual clinical need.

### **Diabetes Type 1**

• Self-monitoring and self-adjustment of dosage is recommended in type 1 diabetes according to an agreed action plan with a health professional.

### **Respiratory diseases**

### Asthma and chronic obstructive pulmonary disease

• Self-monitoring in asthma and COPD and self-adjustment of dosage is recommended according to an agreed action plan with a health professional.

### Chronic obstructive pulmonary disease

• Appropriate patients may benefit from being educated on the benefits of chronic obstructive pulmonary disease rehabilitation, and encouraged to undertake rehabilitation exercise.

*Note:* The evidence base, including references, is provided in Appendix III. Self-care of cardiovascular diseases, diabetes and chronic respiratory diseases, pp127-168 *Source:* World Health Organization 2016 *(unpublished).* 

### Annex 2a. Adapted from the core list of medicines required for implementing essential CVD interventions in primary care

### For Primary Care facilities with Physicians

(for PC facilities with only non-physician health workers most of the medicines below are required for refill of prescriptions issued by physicians at a higher level of care)

- Thiazide diuretic
- Calcium channel blocker (long acting) (amlodipine)
- Beta-blocker
- Angiotensin converting enzyme inhibitor (long acting)
- Statin
- Insulin
- Metformin
- Glibenclamide
- Isosorbide dinitrate
- Glyceryl trinitrate
- Furosemide
- Spironolactone
- Aspirin

- Paracetamol
- Ibuprofen
- Morphine
- Epinephrine
- Heparin
- Diazepam
- Dextrose infusion
- Glucose injectable solution
- Sodium chloride infusion
- Oxygen

PC, primary care

Source: WHO Model List of Essential Medicines, 17th edition. Geneva: World Health Organization; 2011. Adapted from World Health Organization 2010 (8).

### Annex 2b. Essential technology and tools for implementing essential CVD interventions in primary care

### **Technologies:**

### Thermometer

Stethoscope

Blood pressure measurement device\*

Measurement tape

Weighing machine

Glucometer

Blood glucose test strips

Urine protein test strips

Urine ketones test strips

### Add when resources permit:

- Blood cholesterol assay
- Lipid profile
- Serum creatinine assay
- Troponin test strips
- Urine microalbuminuria test strips
- Tuning fork
- Electrocardiograph (if training to read and interpret electrocardiograms is available)
- Defibrillator

### **Tools:**

WHO/ISH risk prediction charts Evidence based clinical protocols Flow charts with referral criteria Patient clinical record Medical information register

Audit tools

Source: World Health Organization 2010 (8).

### Annex 3. WHO and International Society of Hypertension cardiovascular risk prediction charts

WHO/ISH risk prediction chart AFR E and AFR D, for use in settings where blood cholesterol can be measured. 10-year risk of a fatal or non-fatal cardiovascular event by gender, age, systolic blood pressure, total blood cholesterol, smoking status and presence or absence of diabetes mellitus. This charts can only be used in countries of the WHO Region of Africa, subregion E and D.





AFR, WHO African Region; ISH, International Society for Hypertension

Source: World Health Organization (8).

# Annex 4. Clinical and process indicators for implementation of HEARTS

ІМРАСТ									
<b>Number of lives saved</b> Trend in number of lives saved from death due to cardiovascular disease.									
HEALTH SYSTEM CAPACITY									
<b>Coverage</b> Percentage of implementing Primary Health Care centres.	Essential technologies and medicines Trend in numbers of pharmaceutical stock outs reported by each primary health care centre.		<b>Training</b> Percentage of primary health care staff trained annually in NCD prevention and management.						
CLINICAL SERVICES									
<b>Risk assessments</b> Percentage of eligible population with risk assessment completed.	<b>Drug therapy</b> Percentage of high cardiovascular risk (>30%) population receiving statins and/or antihypertensive.		<b>Counselling</b> Percentage of smokers receiving tobacco cessation.						
	PERSPE	CTIVES							
<b>Patient</b> Understanding of WHO Risl Utility of knowing cardiovasc Changes made to health be Participation in community c	ular risk. haviours.	<b>Primary health care providers</b> Ease of using protocols and risk charts. Engagement of patients in community activities. Impact on workload. Changes in own health.							
Ministry of health and hospital services Implementation of protocol nationally. Changes made to workforce development. Impact on hospital services.									
	COMMUNITY	ENGAGEMENT							
<b>Community activities</b> Implementing health care centres with community gardens, treatment groups,									

exercise groups, engaging in advocacy for smoke or alcohol free environments.

## Photo credits

#### **PHOTO P.10**

Rural home where owner died from complications of diabetes. United Republic of Tanzania. Photo: WHO/Chris Bode

### **PHOTO P.13**

Men doing early morning exercise in Mumbai, India. Photo: WHO/Atul Loke

### **РНОТО Р.14**

A doctor examines a patient ECG in Hanoi, Viet Nam. Photo: WHO/Quinn Mattingly

### **PHOTO P.20**

Woman exercising in Bahia, Brazil. Photo: WHO/Eduardo Martino

### **PHOTO P.24**

A dietary specialist conults with patient on healthy eating choices in Ho Chi Minh City, Viet Nam. Photo: WHO/Quinn Mattingly

### **PHOTO P.28**

A patient's blood pressure is checked in a rural commune health centre in Doi Son, Ha Nam Province, Viet Nam. Photo: WHO/Quinn Mattingly

#### **PHOTO P.32**

Patient collects his medicines at a government initiated Kamala Raman Nagar dispensary, India. Photo: WHO/Atul Loke

### **PHOTO P.36**

A health worker uses a CVD risk chart in Manila, Philippines. Photo: Rammel Martinez

### **РНОТО Р.41**

A patient's blood sugar is checked at the National Hospital of Endocrinology in Hanoi, Viet Nam. Photo: WHO/ Quinn Mattingly

### PHOTO P.42

Health worker checking weight during a clinic visit in Lagos, Nigeria. Photo: WHO/Andrew Esiebo

#### **PHOTO P.47**

A health worker listens to a patients heart with a stetoscope in Tajikistan. Photo: WHO/Christopher Black

#### **PHOTO P.48**

In a health-care facility, women take notes in a registry, Nepal. Photo: WHO/SEARO



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