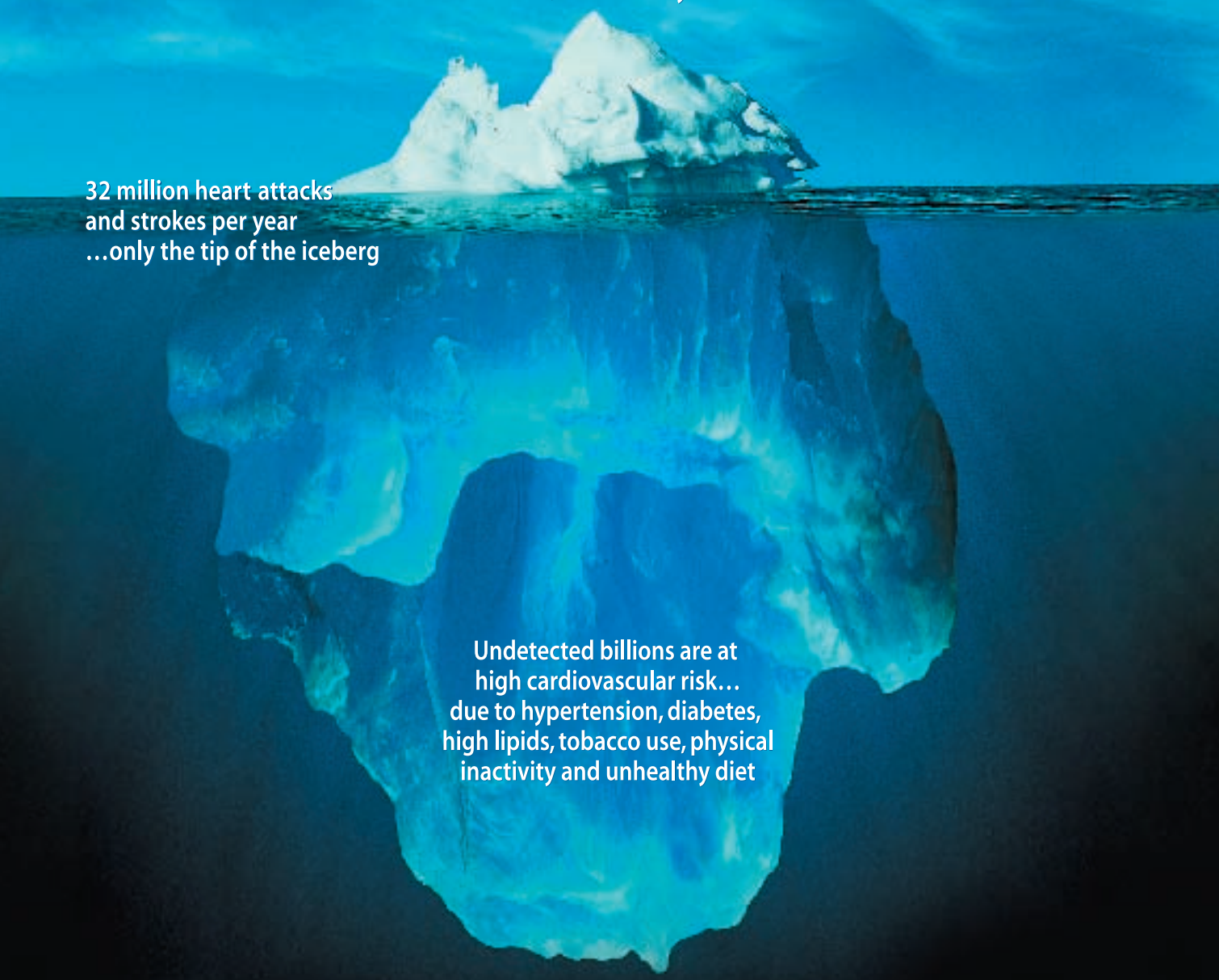
Integrated Management of Cardiovascular Risk

Report of a WHO Meeting
Geneva, 9–12 July 2002



Noncommunicable Diseases and Mental Health
World Health Organization

CVD

Cardiovascular Disease Programme

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This meeting report on "Integrated Management of Cardiovascular Risk" was produced under the direction of Shanthi Mendis, Coordinator, Cardiovascular Disease and staff of WHO/MNC/CVD, in consultation with other WHO staff and external advisors who participated in the meeting. The WHO CVD-Risk Management package developed at the meeting is a separate WHO publication.

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Executive Summary

Cardiovascular disease (CVD) is a leading cause of mortality and is responsible for one-third of all global deaths. Nearly 85% of the global mortality and disease burden from CVD is borne by low- and middle-income countries. In India, for example, approximately 53% of CVD deaths are in people younger than 70 years of age; in China, the corresponding figure is 35%. The majority of the estimated 32 million heart attacks and strokes that occur every year are caused by one or more cardiovascular risk factors – hypertension, diabetes, smoking, high levels of blood lipids, and physical inactivity – and most of these CVD events are preventable if meaningful action is taken against these risk factors.

Regrettably, CVD prevention too frequently focuses on single risk factors, rather than on comprehensive cardiovascular risk. For CVD prevention activities to achieve the greatest impact a paradigm shift is required, away from the treatment of risk factors in isolation, to a comprehensive cardiovascular risk-management approach. Evidence-based, cost-effective interventions are available for addressing comprehensive cardiovascular risk, and the challenge now is to "use what we know", particularly in low- and middle-income countries. This calls for resource-sensitive, innovative strategies.

> The objective was to develop a package to facilitate CVD risk management in under-resourced settings

To address this task, WHO convened a meeting, "Reduction of cardiovascular burden through cost-effective integrated management of cardiovascular risk: addressing hypertension, smoking cessation and diabetes". Participants included health-care providers with hands-on experience in low-resource settings; international experts; representatives from WHO Regional Offices; non-governmental organizations; and private-sector representatives.

The objective of the meeting was to refine a package of tools for comprehensive CVD risk management in under-resourced settings in developed and developing countries. The package informs policy-makers of the need to address CVD risks and the feasibility of doing so using an appropriate programme. The package utilizes affordable approaches for CVD risk management, and promotes rational resource allocation, evidence-based nonpharmacological treat-

ment and cost-effective generic drugs. The package also includes self-management strategies.

If the package is to reach its full potential in achieving better health outcomes, many changes must be brought about in health policy, health systems, health providers, patients and their families. One barrier to the successful implementation of the package is the limited health infrastructure of low- and middle-income countries, including the scarcity of basic equipment such as blood pressure measuring devices (BPMDs). The relative advantages and disadvantages of mercury, aneroid and automated BPMDs were discussed at the meeting and recommendations on the appropriate selection of these devices were issued. In collaboration with relevant partners and private industry, WHO will explore the possibility of developing an accurate and inexpensive automatic BPMD for worldwide use.

To take this initiative forward, the next steps will include an evaluation of the components of the package in field-based pilot studies. The tools are expected to gradually evolve over time, with the experience of their use in real settings. If this initiative is to contribute to reducing the global CVD burden, commitment from all stakeholders, both at international and national levels, is essential.

1 Setting the scene

1.1 Background

CVDs are responsible for the deaths of 17 million people each year, or approximately one-third of global deaths annually (*1, 2*). Hypertension is the most prevalent CVD, affecting at least 600 million people, and is an important contributor to cardiovascular mortality and morbidity (*3*). In recognition of the burden posed by hypertension, WHO and the International Society of Hypertension have just completed the *2002 World Health Organization and International Society of Hypertension Guidelines on Management of Hypertension*, which is based on explicit evidence-based methodology (*4*).

Although the concept of applying evidence-based medicine to clinical practice seems simple, there are many issues to consider. Several studies, for example, have demonstrated low rates of compliance with evidence-based treatment guidelines for managing hypertension (*5, 6*). Furthermore, conventional management of hypertension leaves patients at an unacceptably high risk of cardiovascular events, due to suboptimal blood pressure control and failure to address coexistent cardiovascular risk factors (*7, 8*). These findings call for a paradigm shift from "treatment of hypertension" to "management of comprehensive cardiovascular risk." This shift is also supported by evidence that the cost-effectiveness of managing hypertension is influenced by the overall risk of CVD among patients, not simply by their blood pressure (*9, 10*).

In many settings, the management of hypertension is suboptimal, mainly due to barriers related to patients, health-care providers and the health system (*5, 11, 12*). Furthermore, the management of cardiovascular risk, compared to treating elevated blood pressure *per se*, demands more skills and better-maintained and better-equipped facilities. To facilitate this task, flexible tools need to be developed which can be applied in many situations. The accurate measurement of blood pressure is also fundamental to the management of cardiovascular risk, and although there are nearly 500 automatic BPMDs in the market, only about 15 have been validated (*13*). Furthermore, due to mercury toxicity, conventional sphygmomanometers are being phased out of production, resulting in the need to develop accurate and affordable BPMDs for under-resourced settings (*14*).

> A balanced combination of population-wide and high-risk preventive strategies is vital for effective control of the CVD epidemic

1.2 Rationale and goals of the meeting

In view of the above, WHO/CVD programme considered it timely to convene a meeting to develop a package of flexible tools for cardiovas-

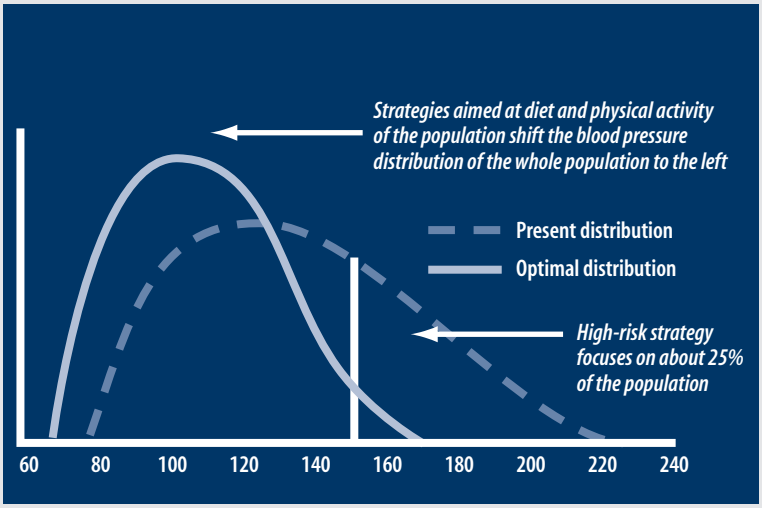
cular risk assessment and management based on the 2002 WHO/International Society of Hypertension management guideline (*4*), and also to issue recommendations on the choice of BP-MDs, particularly for underresourced settings. As a result, a WHO meeting on "Reduction of cardiovascular burden through cost-effective integrated management of cardiovascular risk: addressing hypertension, smoking cessation and diabetes" was held in Geneva, Switzerland on 9–12 July 2002. The meeting was organized by the Cardiovascular Disease Programme in collaboration with other WHO programmes within the Noncommunicable Diseases and Mental Health Cluster (including those for Diabetes, Innovative Chronic Care and Adherence, and the Tobacco Free Initiative). Also involved in the collaboration were Noncommunicable Diseases Prevention and Promotion Department; Surveillance; the Evidence and Information for Policy Cluster (Health Facilities and Services Provision); and the Health Technology and Pharmaceuticals Cluster.

The "high-risk" approach that is the focus of this meeting is complementary to WHO's ongoing population-based approaches for preventing noncommunicable diseases that target tobacco, diet and physical activity. Indeed, a combination of high-risk and population-based strategies are essential to shift the cardiovascular risk profile, including the blood pressure profile of the population, to a more favourable distribution (Figure 1).

The added value of a comprehensive cardiovascular risk assessment and management package sensitive to different resource settings and to patient and provider needs was identified as the following:

- Facilitating a paradigm shift from single risk factor management to comprehensive cardiovascular risk management through simplified clinical pathways.
- Promoting evidence-based nonpharmacological treatment of cardiovascular risk and operationalizing clinical prevention aided by counselling protocols.
- Enabling cardiovascular risk management (in settings faced with low resources) through affordable approaches and rational resource allocation.
- Promoting the use of cost-effective generic drugs for managing cardiovascular risk.
- Empowering patients and their families to cope with a long-term illness through self-management tools.
- Informing policy-makers of the need and feasibility of managing cardiovascular risk in less well-resourced settings.

▼ Figure 1
Present and optimal distribution of systolic blood pressure in adults. A combination of population and high-risk strategies for blood pressure control is necessary to achieve the optimal blood pressure distribution.



1.3 The meeting process and participants

Brief presentations were given by participants from low- and middle-income countries and discussions were based on the working document. Cardiovascular risk assessment and management pathways, smoking cessation, diet and physical activity counselling protocols and tools for adherence were included in the working document. The protocols and tools were revised through group discussions, and finalized through plenary discussions.

Participants reflected a wide range of expertise in the management of cardiovascular risk at different levels in the health-care systems in low-, medium- and high-income countries. Participants included representatives from research foundations and nongovernmental organizations working in hypertension, diabetes and gender-related issues. Representatives from industry were invited as observers and, although their input was necessary, it was limited to exploring the possibility of developing an accurate, affordable BPMD for low-resource settings. Industry representatives did not participate in any sessions that issued recommendations on the use of devices and the management of cardiovascular risk. All participants were required to disclose potential conflicts of interest.

Dr. Derek Yach, Executive Director of the Noncommunicable Diseases and Mental Health Cluster opened the meeting and summarized a number of issues relevant to the deliberations:

> "The intermediate manifestations of unhealthy consumption patterns, including hypertension, diabetes and high lipids, often occur together and affect more than a billion people in the world. The health outcomes of these patients can only be improved through an integrated approach to the management of overall cardiovascular risk. This requires a better and enhanced focus on cardiovascular risk management and should result in efficient use of limited resources and also ensure those opportunities for clinical prevention, such as counselling for smoking cessation or better dietary practices, are not missed.
>
> "There are numerous barriers to delivering integrated care for chronic diseases, particularly in low-resource settings: shortage of health-care providers; lack of capacity for policy development; poor adherence to long-term treatment; inappropriate drug policies; weak infrastructure; inadequate information systems; and ineffective resource allocations.
>
> "Overcoming these barriers in resource-constrained environments is a major challenge and calls for innovative strategies, such as the ones that are being addressed at the meeting."

1.4 The package in the context of other WHO programmes for noncommunicable diseases

As explained above, the WHO CVD-Risk Management Package provides a flexible approach for the assessment and management of CVD in settings with different resource levels. It is synergistic to another priority project of the CVD programme aimed at scaling-up secondary prevention of myocardial infarction and stroke. The package can be viewed as part of a comprehensive WHO approach to address the rising burden of noncommunicable diseases. For example, WHO has been successful in placing tobacco high on the global public-health agenda through its work on the Framework Convention on Tobacco Control. Work is also in progress to develop a global strategy for promoting healthy diet and physical activity, for advancing innovative care for chronic conditions and for establishing surveillance systems for noncommunicable diseases.

In addition, the World Health Report 2002 (*2*) focuses on risks to health and provides compelling evidence of the need to take firm actions against the risk factors common to cardiovascular diseases, diabetes, cancers and chronic respiratory diseases: tobacco, alcohol, physical inactivity and unhealthy diet.

The remaining sections of this document outline what is known about cardiovascular risk, highlight the barriers to addressing cardiovascular risk management in low-resource settings and elaborate the proposed package of tools to facilitate this task in such settings.

2 The challenge

2.1 Scope of the problem

CVD is an important cause of global morbidity and in five of the six WHO Regions it is the leading cause of mortality (Table 1).

As health surveillance systems improve in nonindustrialized countries, there is an emerging awareness of the magnitude of CVD as a cause of premature mortality. This is also true for industrialized societies, and in several regions there has been a rapid increase in CVD rates over the last two decades (notably in Eastern Europe and the former Soviet Union; *15–18*). In many countries of Asia and Africa limited data have been available on detailed CVD mortality patterns (*19–22*). Nevertheless, it is now widely recognized that stroke is a major cause of death among the elderly and myocardial infarction is an important public-health problem in urbanized populations of these regions.

> We now have the required base of science and technology to effectively reduce the public health impact of CVD – Let us `use what we know`

2.2 Importance of prevention of myocardial infarction and stroke

Of the estimated 32 million heart attacks and strokes that occur globally each year, about 12.5 million are fatal (1). In both developed and developing countries, 40%–75% of all heart-attack victims die before reaching hospital (23, 24). Preliminary studies in sub-Saharan Africa and the Caribbean indicate that case fatality rates from stroke are 2 to 3 -fold higher than those in developed countries (22), and this has been attributed to limited health-care facilities and untreated risk factors, including hypertension.

◀ Table 1
CVD-related deaths for 2001, by WHO region

Source: (2). Deaths are given in thousands.

CVD	African Region	American Region	European Region	South-East Asia Region	Western Pacific Region	Eastern Mediterranean Region	World
Cerebrovascular disease	307	454	1 480	1 070	1 926	218	5 455
Ischaemic heart disease	333	967	2 423	1 972	963	523	7 181
Hypertensive heart disease	54	131	175	138	285	91	874
All CVDs	**985**	**1 979**	**5 042**	**3 797**	**3 745**	**1 037**	**16 585**

Even in settings where advanced technology and facilities exist, the prognosis for those who have suffered strokes is poor, with 58% dying or becoming dependent on their families and/or society (*25*). Given these dismal statistics and the high cost of treating acute events, high priority should be given to preventing strokes and heart attacks, rather than simply treating them, particularly in developing countries in which resource-intensive care is not a feasible option.

2.3 "Use what we know"

Advances in cardiovascular epidemiology in developed countries provide the knowledge base necessary to understand the underlying biological processes that account for these emerging epidemics (*26, 27*). There is no doubt that available prevention and treatment modalities, for smoking cessation, hypertension and diabetes, apply equally in all human societies. The challenge, however, remains one of fashioning appropriate strategies that can achieve practical success under the highly varied conditions in low-income countries. Thus, wholesale transfer of the methods of intervention is less likely to be successful and extensive local adaptation will be required.

Despite the predictions of a global CVD epidemic, we stand on the threshold of a new era in our attempts to control CVD. There is robust evidence on the value of primary and secondary prevention interventions for controlling CVD (*4, 28-30*). In patients who have already experienced a CVD event, for example, a range of interventions is available that can markedly improve prognosis (*31–33*). For diabetes, a change in lifestyle (defined by weight loss and increased activity) has been shown to reduce cardiovascular risk significantly (*34*). Combining all of these strategies now makes it possible to conceptualize a programme of CVD control on the scale of the smallpox and polio campaigns. Collectively, we now have the required base of science and technology to effectively reduce the public-health impact of CVD. However, as

▶ Figure 2
A multiple CVD risk factor approach is imperative for effectively controlling the global CVD epidemic

▶ **Table 2**
Contribution of health risks to global mortality, 1990

Health risk	Contribution to global mortality (%)
Tobacco use	6.0
Hypertension	5.8
Inadequate water and sanitation	5.3
Risky sexual activity	2.2
Alcohol use	1.5

the European Action on Secondary Prevention by Intervention to Reduce Events (EUROASPIRE I and II) has demonstrated, even in developed countries there is substantial potential for improving prevention in clinical settings and for implementing evidence-based clinical practice (*35*). The challenge can be summarized as the need to "use what we know."

2.4 Cardiovascular risk

The enormous opportunities available must be balanced against the magnitude of the challenges. Although heart attacks and strokes are leading causes of death and disability, they represent only the tip of an iceberg. Indeed, all societies that adopt an industrialized lifestyle have seen the emergence of CVD risk factors on a mass scale. These modifiable risk factors (i.e. smoking, unhealthy diet and physical inactivity) are expressed as hypertension, diabetes, obesity and high blood lipid levels, and together contribute to the total cardiovascular risk and are the root causes of the global CVD epidemic (Figure 2). In 1995, for example, it was estimated that there were 1.1 billion smokers worldwide and tobacco contributed to 3 million deaths (36, 37). In 2001, tobacco-related mortality was 4.9 million and this figure is estimated to reach 10 million by 2020 if appropriate action is not taken (2). These deaths were mainly due to CVD and lung cancer and were preventable.

Although the relative importance of these risk factors may vary in different populations, these conventional risk factors account for 75% of the CVD epidemic worldwide (38). Not only do we understand the causal pathways between these risk factors and CVD, we have extensive evidence that, when action is taken against the risk factors, the catastrophic consequences of this rapidly growing epidemic can be avoided.

2.5 Hypertension as an entry point to cardiovascular risk management

About 15%–37% of the adult population worldwide is afflicted with hypertension (*39–42*). In those older than 60 years of age, as many as one-half are hypertensive in some populations (*43*). In general, hypertension prevalence is higher in urban settings compared to rural settings (*44*). Furthermore, because of the asymptomatic nature of the condition most hypertensives are unaware they are affected. In 1997, an assessment commissioned for the WHO Ad Hoc Committee on Health Research estimated the percentage of deaths globally that were associated with common risk factors (*45*). For 1990, smoking and hypertension were the major causes of global mortality (Table 2). Data from World Health Report 2002 (*2*) indicate that hypertension is the third most important contributor to the global disease burden

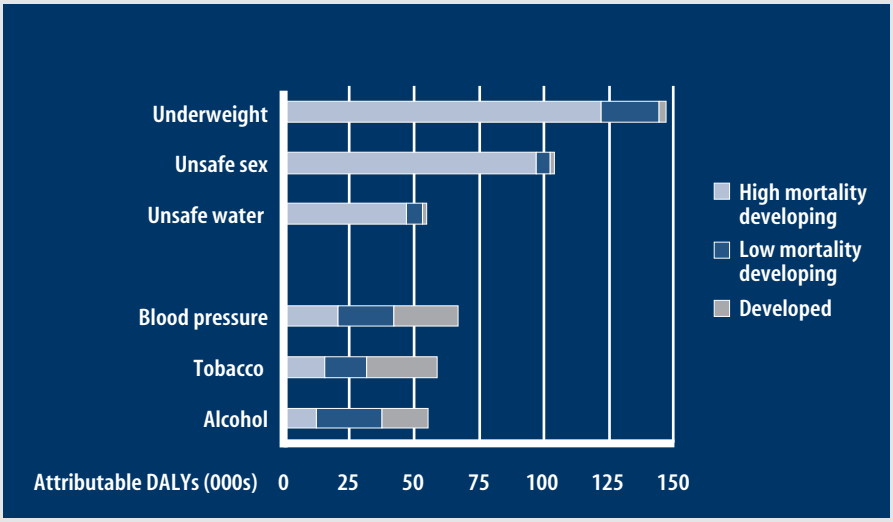
among the six risk factors: underweight, unsafe sex, hypertension, unsafe water, tobacco and alcohol (Figure 3).

It is important to note that for several countries in Asia and Africa, increases in blood pressure and tobacco use preceded the impact of nutrition transition by decades. This has led to high levels of stroke and increasing rates of lung cancer, but relatively low levels of coronary heart disease. This provides an opportunity to implement strong preventive programmes on nutrition and physical activity and suggests that the clinical focus in such countries needs to be more on blood pressure and tobacco use.

The effects of hypertension are devastating. If left untreated, hypertension causes stroke, myocardial infarction, cardiac failure, dementia, renal failure and blindness. Every year, some 12 million fatal and 20 million nonfatal strokes and myocardial infarctions occur worldwide, most in low- and middle-income countries (*1, 2*). These outcomes place a severe financial burden on health systems and monopolize scarce health resources (*46–48*). In most countries, myocardial infarction predominates, but in others stroke (haemorrhagic and ischaemic) is the most common cause of cardiovascular mortality. Because of the disability associated with nonfatal strokes, in some countries stroke prevention may have a greater impact than coronary disease prevention. Fortunately, many cardiovascular interventions contribute to reducing the incidence of both stroke and myocardial infarction, and treating hypertension has been associated with a 35%–40% reduction in the risk of stroke and a reduction of at least 15% in the risk of myocardial infarction (*49*). Smoking also markedly increases the risk of cardiovascular disease (*50, 51*), as does diabetes, the prevalence of which continues to rise across the world

The risks for coronary disease, stroke, peripheral vascular disease and amputation of the lower extremities are all increased by diabetes (*52, 53*). In the last two decades, the rise in the prevalence of diabetes (predominantly Type 2) has been dramatic and is expected to continue. Current estimates indicate that about 150 million people have Type 2 diabetes globally and this figure is expected to double by 2025 (*54*). Apart from the increase in absolute numbers, Type 2 diabetes is appearing

▶ Figure 3
Global distribution of disease burden attributable to six major risk factors
Source: (2).



with increasing frequency in young people, including children and adolescents. Similar numbers of people have impaired glucose tolerance, which has also been shown to be associated with a 2–3 -fold increase in vascular disease (*55, 56*). About 75% of the mortality among diabetic men, and 57% among diabetic women, is attributable to cardiovascular disease deaths (*57*). The increase in coronary risk associated with diabetes is much greater for women than for men. It is now clear that, in addition to being associated with an increased prevalence of hypertension and dyslipidemia, the elevated blood-sugar levels characteristic of diabetes is itself associated with a large increase in risk for cardiovascular disease (*52, 53*). Indeed, cardiovascular disease is the most common complication of Type 2 diabetes.

Recent studies from China, Finland and the USA have demonstrated that lifestyle modification can prevent the development of diabetes in those with impaired glucose tolerance (*58, 59*). Other studies have also demonstrated the efficacy of secondary interventions in preventing the progression of diabetes complications, and have emphasized the importance of an integrated approach that focuses on all risk factors, rather than on glucose tolerance alone (*34, 60*).

2.6 Treatment gap

Despite years of action, the detection and control of hypertension remains a challenge even in developed countries. The detection rates in most high-income countries vary from 32%–64% (*61, 62*), while in many low-income countries the reported detection rates are substantially lower (*63, 64*). The control rates in those already on treatment for hypertension varies from 13%–29% (*49, 65, 66*). However, in African countries, control rates were reported to be as low as 2% (*67*). It must be recognized, however, that treatment and control of CVD risk factors do not inherently require enormous resources. Several countries in the Caribbean have made substantial progress, and it has been demonstrated that a well-organized and focused approach on the part of the health system, in a supportive political environment, can achieve satisfactory blood-pressure control with modest resources (*68*).

For a variety of reasons, the strategies for managing cardiovascular risk used in high-income countries are not feasible for most low- and middle-income countries. During this meeting, representatives from developing countries highlighted the obstacles that currently exist in low-resource settings and some of these are presented in the next section.

3 Country situations

A highlight at the meeting was the presentation of a study on Nigeria and summary reports from Cameroon, Mozambique, Pakistan and Thailand. Some basic demographic, socioeconomic and health expenditure data from these countries are shown in Table 3.

The presentations from these countries demonstrate the current situation with respect to cardiovascular risk management, as well as factors that most likely influence management outcomes, such as individual, family and community access and adherence to care; capacity for self-management; and responsiveness of health-care facilities to CVD risk-management need. The reports underscored the service delivery gaps in the care of CVD and CVD risk.

> Of the estimated 16.6 million deaths attributed to CVD worldwide, 80% is in developing countries

3.1 Hypertension management in Nigeria

The Nigerian study, conducted in two local Government areas of Oyo State, reported on data obtained from 632 consecutive hypertensive patients attending outpatient clinics, 43 public and private health-care facilities, and health-care providers in these facilities, as well as 19 community development committees in communities in which the health-care facilities were located. The data represented work-in-progress, as only preliminary analysis was presented at the meeting.

According to the findings, most patients (98%) paid out-of-pocket for prescriptions, and as much as 84% of the sample paid for consultations and drugs. Nonphysician health workers appeared to play important roles in improving knowledge about health, as well as in the exchange of health information and in promoting self-motivated blood pressure monitoring. Drug prescription patterns (and drug use) indicated a lack of resource–conscious drug management policy. The inability to afford drugs was cited as a major reason for not taking prescriptions as advised, four weeks prior to the study.

The report showed that facilities are underequipped with instruments and equipment relevant to CVD risk management; have poor equipment maintenance policy; and were poorly-responsive to patients needs. For example, only 30% of the sampled health-care facilities were equipped for urinalysis; 21% for fasting blood sugar measurement; 16% for serum electrolyte estimation; 9% for total cholesterol and lipoproteins measurement; and 7% for electrocardiography. In contrast, the majority of facilities (74%) had mercury sphygmomanometers; 30% had aneroid devices; and 7% had digital sphygmomanometers. However, as many as 11% of the facilities did not have any BPMDs.

The report concluded:

- There was less-than-adequate CVD risk assessment at the point of health-care delivery.

- The cost burden is mainly borne by the patients, which underscores the importance of affordability and of taking resource-sensitive approaches to management.
- Patients appear to have appreciable risk-modifying information-exchange contacts, and that nonphysician health workers play an important role in these contacts.

3.2 Constraints to hypertension management in Cameroon, Mozambique, Pakistan and Thailand

Reports from the other countries indicated broad similarities in the CVD risk-management status and gaps. The report from Pakistan showed that the cost of a monthly prescription for hypertension ranges from 50%–200% of monthly income per capita, similar to the situation in India. The report also showed that geographical inaccessibility compounds the barriers to health-care access.

In Mozambique, noncommunicable diseases were reported to be responsible for up to 22% of all deaths, and stroke was the leading cause of death among the over-60 years of age group. There was very poor access to health care, and as much as 60% of the population did not have easy access, even to a nonphysician health-care provider. There were only about 400 physicians to 18 million people living in Mozambique and the majority of them were practicing in urban health-care facilities.

Reports from Cameroon and Thailand showed that the situation was similar to that in most low- and middle-income countries. For instance, poor access to health care and health-care providers were major impediments to CVD risk management in Cameroon. In Thailand, reorganization of the health system is underway, to make it more responsive to CVD risk-management needs. It was concluded that this package would facilitate some of the ongoing changes in the system process.

Finally, meeting participants endorsed the need for a "cardiovascular risk assessment and management package" to facilitate CVD care in underresourced settings. They also proposed that model projects be developed to integrate the package into routine CVD care in health systems, particularly those of low- and middle-income countries, with the long-term goal of nation-wide extension.

▶ Table 3
Demographic, socioeconomic and health expenditure data for Cameroon, Mozambique, Nigeria, Pakistan and Thailand

Source: (2).

Country	Population (millions)	GDP/Capita	Per capita total health expenditure (US $)
Cameroon	15.4	2 000	17
Mozambique	15.7	670	8
Nigeria	125.0	1 380	5
Pakistan	144.6	2 000	18
Thailand	62.0	2 168	71

4 Paradigm shift

from single risk factor approach to comprehensive cardiovascular risk management

To make a tangible difference in CVD morbidity and mortality, a paradigm shift is needed from the management of hypertension to the management of comprehensive cardiovascular risk. Among the leading causes of disease burden, both in developed and developing countries, are risk factors that are also responsible for CVD (Table 4).

Until recently, treatment strategies have encouraged health providers to treat, for example, "hypertension" and "hypercholesterolemia", despite emerging evidence that these two risk factors, in addition to hyperglycaemia, are associated with a continuous elevation in risk of cardiovascular disease, across the range seen in populations. In addition, at any given level of blood pressure and blood glucose, the risk is higher in smokers (*28, 69–71*; Figure 4).

Increasingly, the very terms hypertension, hyperglycemia and hypercholesterolemia will probably disappear, as the focus moves from treating a theoretically decided cut-off point, towards managing continuous distributions of risks that intersect and interact with each other: blood pressure, blood sugar and blood cholesterol should be the focus of control.

> An absolute cardiovascular risk approach is required to make treatment of hypertension cost-effective and to improve health outcomes

Since interventions shown to reduce CVD lead to a proportional reduction regardless of the absolute level of risk, treating individuals and populations at highest risk is most efficient,

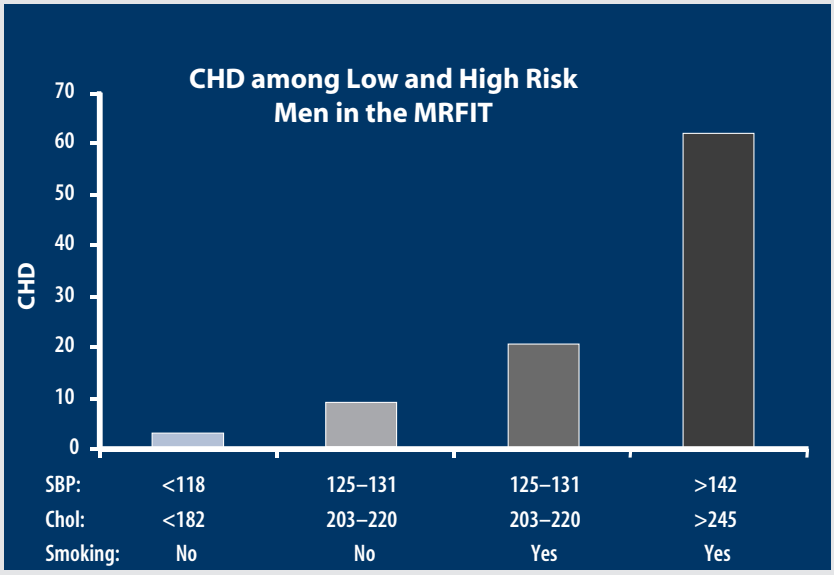
◀ Table 4
Ten leading selected risk factors as causes of disease burden

Source: (2). *CVD risk factors are shown in italics.*

	Developing countries		Developed countries
Rank	**High mortality**	**Low mortality**	
1	Underweight	*Alcohol*	*Tobacco*
2	Unsafe sex	Underweight	*Blood pressure*
3	Unsafe water	*Blood pressure*	*Alcohol*
4	Indoor smoke	*Tobacco*	*Cholesterol*
5	Zinc deficiency	*Body mass index*	*Body mass index*
6	Iron deficiency	*Cholesterol*	*Low fruit and vegetable intake*
7	Vitamin A deficiency	Iron deficiency	*Physical inactivity*
8	*Blood pressure*	*Low fruit and vegetable intake*	Illicit drugs
9	*Tobacco*	Indoor smoke from solid fuels	Underweight
10	Cholesterol	Unsafe water	Iron deficiency

▶ **Figure 4**
Increased cardiovascular risk associated with multiple cardiovascular risk-factor profiles

Source: (72).

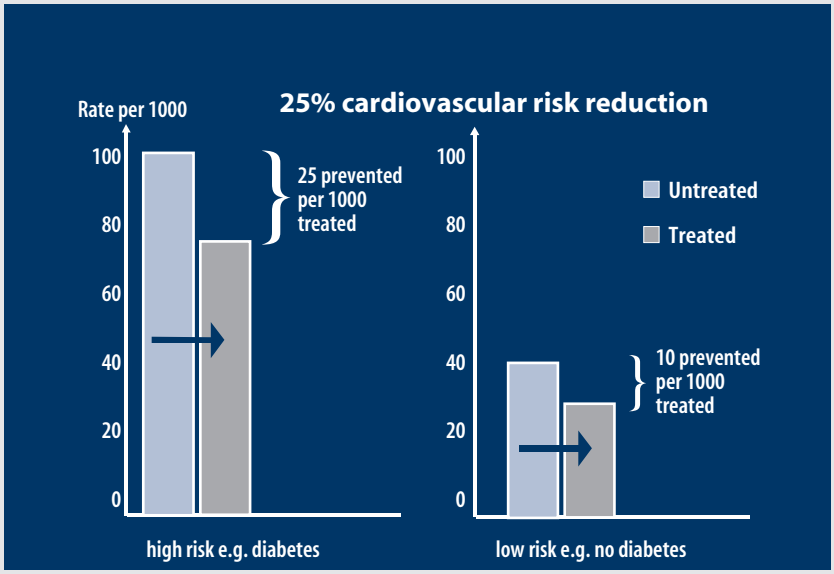


since for the same number of people receiving treatment, more people are likely to benefit (*4, 28*). As such, this strategy is also the most cost-effective. An example is presented in Figure 5.

4.1 Barriers to comprehensive cardiovascular risk assessment and management

Several studies have demonstrated that conventional management of hypertension leaves patients at an unacceptably high risk of cardiovascular and other complications, such as myocardial infarctions, strokes, cardiac failure, renal failure and death (*7, 72*). This appears to be due mainly to suboptimal blood pressure control and failure to address other coexistent risk factors that contribute to total cardiovascular risk (*8*). These findings demand a paradigm shift from "treatment of hypertension" to "management of comprehensive cardiovascular risk." In

▶ **Figure 5**
The need for comprehensive risk assessment



addition, the cost-effectiveness of treating hypertension is also determined by the overall cardiovascular risk and not by blood pressure alone (*9, 72, 73*).

While recognizing the need for major changes in the approach of the health system to controlling CVD risk factors, it must also be acknowledged that structural problems are basic obstacles, including limited financial resources for primary care. When countries with low GDPs can only devote 2% of the their meagre budget to health care it is understandable that achievements will remain limited. Furthermore, in most health-care systems, health-care costs are often covered by out-of-pocket expenditure. Thus, cardiovascular risk assessment and management need to be resource sensitive.

The commitment of health professionals and professional associations is vital to bring about a paradigm shift from a single approach to one involving multiple risk-factor intervention. Although the importance of comprehensive cardiovascular risk assessment and management has long been recognized, the medical fraternity has not been active enough to bring about the desired changes in clinical practice.

4.2 Assessing the impact of cardiovascular risk factors

Cardiovascular risk factors will pose a hazard to health regardless of the social setting. Nonetheless, the size of that impact, in both relative and absolute terms, may vary. Although data are critical for determining the impact of cardiovascular risk factors, for most low- and middle-income countries the necessary data are not available. Whether any resources should be spent on surveys, or reserved for interventions, will remain a subject of debate. Given the resource constraints in low- and middle-income countries, it is doubtful whether this scenario will change appreciably in the near future. Approximations and inferences must therefore be made from existing data from other countries (Table 5).

The overall risk (so-called "global risk assessment") for the individual cannot be determined by looking at each factor separately; instead comprehensive risk stratification is required (Figure 5). Obviously, a smoker with high cholesterol and hypertension is at higher risk and is more likely to have a myocardial infarction than a person with hypertension alone, and treatment will have a greater effect with patients in the former group.

4.3 Applying cardiovascular risk assessment to low-resource settings

Health systems in low-income countries may not have sufficient resources to support resource-intensive risk stratification systems. To date, the most common application of risk stratification is as a tool to guide decisions on cost-effectiveness. Given options, it is more rational to choose a treatment programme that will produce the greatest benefit to patients. After a decision has been made regarding the gen-

Risk factor	Prevalence (%)	Relative risk	Attributable risk (%)
Smoking	30–40	2.0	20
Hypertension	10–30	1.5–2.0	5–10
Diabetes	5–10	2.0–2.5	10

◀ Table 5
Approximate prevalence, and relative and attributable risks related to hypertension, smoking and diabetes

eral level of cost-effectiveness that is acceptable within a health system, risk stratification can help identify the appropriate patients that require treatment. To apply this method, however, it is necessary to have evidence from epidemiological studies on the absolute risk that patients in various categories would experience. Unfortunately, these data do not exist in virtually all developing country settings. Under such conditions, risk stratification can serve only a more limited purpose.

Given a level of expenditure that represents the current reality, risk stratification can help identify the subset of patients most in need of treatment. It is important in this context, however, not to confuse this triage application with a cost-effectiveness analysis. As a result of a formal cost-effectiveness study, the group of patients that would benefit from treatment might be much larger than those whom current budgets can accommodate. It is imperative therefore, that the necessary epidemiological data be obtained so that future decisions can be based on evidence. In the interim, recognizing extremely severe budget constraints and the virtual absence of consistent treatment for the poor in these countries, risk stratification serves as a "rule of thumb" method for triaging those most in need.

Many risk-stratification systems have been developed and all have limitations (69, *70, 73–75)*. For example, although the Framingham function provides an accurate *ranking* of cardiovascular risk in most populations, it is inaccurate as a measure of *absolute* risk. Furthermore, the measurement of certain variables for this risk-stratification system (e.g. cholesterol and HDL cholesterol) may not be readily available in some settings or may be unaffordable. Thus, feasible risk-assessment methods need to be devised that use simple clinical indicators – such as age, sex, smoking habits, history of premature CVD in the family, presence or absence of diabetes, and presence or absence of hypertension – that are measurable in less well-resourced settings. With this information, it is possible to develop a pragmatic risk-stratification system to rank people with mild hypertension into low-risk and high-risk groups in order to make treatment decisions. Such systems, although they may be less accurate, are likely to be the only feasible option in such contexts.

4.4 Limitations in advocating estimation of individual risk for future cardiovascular events

Due to limited resources, it is logical to treat the patients at greatest risk of CVD and therefore with the most to gain, but assessing individual risk is frequently problematic. It may not be possible to generalize existing algorithms, which have been developed in the United States, United Kingdom, France and Germany, to other countries where, for example, stroke may be the predominant CVD (*2*). Furthermore, current algorithms do not take into account factors that decrease risk, such as healthy behaviour or coexisting pharmacological therapies. In addition, algorithms incorporate measures not available in all settings, such as blood lipid levels.

Thus, a pragmatic risk-stratification approach, which takes into consideration the above limitations, is timely. The accompanying CVD-Risk Management Package includes a risk-stratification procedure that can serve as a starting point and as a template to be customized for health systems in low-resource settings. In addition, if such an approach to cardiovascular risk management is to be sustainable, critical focal areas related to health systems and their organization need to be addressed.

5 Relative balance

between population strategy and high-risk strategy for primary prevention

Epidemiological theory indicates that, compared with intensive individual treatment of high-risk patients, small improvements in the overall distribution of risk in a population will yield larger gains in disease reduction, when the underlying conditions that confer risk are widespread in the population (*76*). However, the CVD-Risk Management Package is designed to select and target high-risk patients because of resource considerations. Consequently, when implementing the package it is imperative that adequate measures are taken to address low-risk individuals through population strategies.

Under such circumstances it is important not to create a false antagonism between the approaches, but rather to use both to their maximal and complementary advantages. A high-risk strategy is necessary to target the 15%–37% of the population with elevated blood pressure. On the other hand, population approaches benefit the whole population and help to shift the population distribution of blood pressure to lower levels. For example, removing particular fats from the food chain or lowering salt used in processed foods would have an influence on the blood pressure of the whole population. In low-resource settings the population approach has obvious appeals and should be given the highest priority. Substantial savings would occur in populous nations if cigarette use or nutritional patterns could be altered through policy, as opposed to one-on-one treatment programmes. Unfortunately, those countries in need of health-oriented policy are often those with the weakest regulatory structure, and have the greatest dependence on market forces outside their control. Nonetheless, a constant effort needs to be made to keep cigarette control, reduction in salt consumption and appropriate use of cooking oils on the top of the agenda for preventing CVD in developing countries.

> 50% of death and disability from CVD can be reduced by a combination of simple effective national efforts and individual actions to reduce major cardiovascular risk factors

An important advance in prevention science in recent years is the proof that nonpharmacological methods of treating elevated risk factors are efficacious, even after the risk factors have been established. Randomized trials have shown that an 11 mmHg reduction in systolic blood pressure can be achieved with a diet that included 50 mEq of sodium, generous portions of fruits and vegetables and low-fat dairy products (*77*). Large trials have also shown a 58% reduction in the incidence of diabetes among high-risk patients with mild weight loss and exercise (*58*). While it is acknowledged that these interventions are not necessarily simple or cheap to carry out, this evidence provides a solid basis for launching programmes to demonstrate effica-

cy and feasibility of these procedures in low-income countries.

Simple and effective treatment of patients with risk factors should now become a reality for health systems in all parts of the world. Given the evidence regarding the scope and projected increases of the CVD epidemic in low-income countries, it is no longer possible to side-step the obligation to transfer established treatment methods for hypertension, diabetes and hypercholesterolemia to these countries. Inexpensive and effective generic drugs, such as thiazide diuretics, beta-blockers and oral hypoglycemics are available for managing hypertension and diabetes. Although statins and angiotensin-converting enzyme inhibitors are currently too costly for widespread use, their effectiveness needs to be recognized. They have been shown to lower the risk of CVD by 25%, regardless of the reason for the risk elevation (*78–80*) Specifically, statins have been shown to lower the risk of heart disease and stroke at so-called normal cholesterol levels (*79*), and angiotensin-converting enzyme inhibitors are effective at normal levels of blood pressure (*78*). These findings imply that statins can be prescribed to high-risk patients to prevent heart attacks and strokes without measuring cholesterol, with implications for potential economic savings. With statins gradually losing patent protection it will become more feasible to incorporate them in the management of CVD risk, even in low-resource settings.

If we are to move forward from virtually no treatment, to a standard where CVD care is an integral part of health practice at all levels, then major changes must occur in the health system at the levels of policy, organization, training and facilities. Furthermore, practical tools are required to improve the ability of healthcare systems in low-resource countries to address the needs of patients with CVD. The following section highlights the major barriers to change and provides supporting arguments for the changes that must occur to create a context for the successful use of CVD tools.

6 Barriers
to cardiovascular risk management

6.1 Health policy

The overriding barrier to CVD risk-management programmes in low- and middle-income countries is that there are no formal policies that target CVD as a major health issue. In 2001, a survey of 167 countries in the six WHO Regions found that 57% of the countries lacked a noncommunicable disease policy, and 65% had no CVD plan (*81*). Several factors explain the absence of formal policies in such settings: a paucity of epidemiological data documenting the scope of CVD; a focus on communicable diseases; a lack of knowledge about the cost-effectiveness of CVD prevention; and limited human and physical resources. In 1998, for example, total health expenditure was below 5% of the GDP in 85 of the 191 WHO Member States (*82*). Furthermore, per capita health expenditures vary from US$ 4055 in the USA, to US$ 34 in China and US$ 1 in Liberia. The per capita health expenditure of at least 15 Member States is less than US$ 10 (*82*).

Innovative strategies are required to overcome multiple barriers to cardiovascular risk management in low-resource settings

The following would help to address these factors:

- To address the lack of epidemiological data, collaboration should be promoted between research institutions in low- and middle-income countries and in more affluent countries.
- Advocacy is needed to overcome the lack of knowledge surrounding CVD and to communicate both its importance and the availability of cost-effective interventions.
- Policy options are needed that address the limited physical and human resources for CVD prevention and control, including options for enhancing investment in health care and for better utilizing the skills of nonphysician providers.

6.2 Health-care systems

The lack of a health policy for CVD can have many downstream effects, most notably the inadequate allocation of resources to local health systems for CVD management. Other factors that limit CVD risk management at the system level include: underequipped health facilities; a lack of continuity between primary health care and the secondary- and tertiary-care sectors (*11*); poorly-developed information systems; a lack of awareness of the potential health benefits and cost savings of CVD programmes; and the influence of commercial interests on resource allocation. In many low- and middle-income countries, resources are inappropriately channelled to tertiary health care at the expense of lower-level health-care facilities, which are often not provided with basic facilities. This situation needs to be rectified, such

that primary health facilities, which are most accessible to patients, are equipped to provide basic CVD care.

The challenge in providing CVD risk management within primary health care is that this sector has been developed for treating acute, time-limited illnesses and thus does not have information systems to support the patient follow-up necessary for CVD risk management. This can be overcome by facilitating information exchange between patients and their providers through patient-held medical records, and through referral cards documenting a patient's medical history and the indications for referral.

Finally, the commercial interests that shape the purchase of pharmaceuticals and devices have a strong impact on the current provision of CVD care in underresourced settings. Guidance on appropriate use of generic drugs, and the purchase of BPMDs and equipment will help reduce this undesirable influence. Hence, there is a need to develop a basic list of essential medicines and equipment for CVD risk assessment and management that should be available in all primary health-care settings. This list can then be upgraded for secondary and tertiary care to reflect the service needs.

6.3 Health-care providers

The major challenges for health-care providers in delivering a comprehensive CVD risk-management programme are the lack of personnel with appropriate training and skills, and an already overburdened workforce. In the WHO global capacity assessment survey (*81*), health-care professionals received no training in the management of noncommunicable diseases in about one-half of the 167 countries surveyed. In general, nurses were the most frequently reported health-care professional available, ranging from a mean of 685 per 100 000 population in the European Region, to 98 per 100 000 population in the African Region. In addition, generalists and primary health-care physicians were more available than cardiologists and specialists in internal medicine.

One long-term strategy to address the issue of human resources is to strengthen the noncommunicable disease components in the medical and nursing curricula in these settings.

6.4 Patients, families and the community

A comprehensive CVD risk-management programme relies upon individual patients adhering to daily drug treatments, accepting lifestyle advice, and returning for follow-up assessments (*12*). Patient adherence needs to be enhanced through the support of family members and the community, yet more often than not families and communities do not get an opportunity to actively participate in patient care. Families and communities need to be empowered to actively participate in patient care, through health education and through community mobilization programmes.

Local food traditions, the acceptability of prescribed exercise regimens, and local rates of poverty and illiteracy all affect a patient's ability to follow given advice. To accommodate this, lifestyle counselling and other programme components will need to be adapted to the local context. Involving community members in the adaptation process will increase the sense of community ownership, thereby increasing patient acceptance.

7 The WHO CVD-Risk Management Package

Given the barriers described in Section 6, it is necessary to develop an innovative approach to cardiovascular risk stratification and management. The challenge has been to cater to a global audience that shares concern regarding a common health issue, but whose specific needs and conditions may differ greatly from region to region. Despite the resource constraints of health systems, cardiovascular risk management can be addressed, at least in part, through a package of tools that explicitly addresses issues of affordability and that are tailored to suit different levels of health infrastructure.

> As the WHO CVD-risk management package uses a pragmatic approach to cardiovascular risk management it can be applied across all levels of care

7.1 How has it been designed and what is it for?

The package is based on best available scientific evidence and takes into consideration the feasibility of applying this evidence in practice. It has been designed for the management of cardiovascular risk in individuals with elevated blood pressure, detected through opportunistic screening. Although it has been primarily designed with hypertension as an entry point, it can be adapted to diabetes or smoking as entry points. The pragmatic approach used offers sufficient flexibility for the package to be applied across all levels of care.

Given the range of settings in which this package will be used, the module has been designed to address three scenarios (Table 6), representing the range of health-care facilities found in low- and medium-resource settings. The scenarios describe the minimum conditions necessary to effectively implement the package in these different settings. The scenarios represent three combinations of essential health resources: facilities and equipment; the skill level of the health worker delivering the programme; and the range of health services, both diagnostic and therapeutic, that are available. For example, Scenario 1 describes the basic prerequisites for CVD risk management at the level of primary care, while Scenario 3 reflects tertiary care in most settings.

The recommendation is for health-care centres to be categorized into the appropriate scenario, depending on the level of available health infrastructure, with subsequent case-management decisions based on the scenario-specific clinical protocols. This process of categorization should facilitate the work both of policy makers and health-care providers by enabling them to quickly identify what set of human and material resources they have at their disposal, and to use them in the most appropriate and cost-effective manner. However, given the variability of conditions across countries and/or geo-

▼ **Table 6.** *Human resources and facilities available in three scenarios with different resource levels*

	Scenario 1	Scenario 2	Scenario 3
Category of health-care worker	Health care worker.	Specially trained nurses. Medical doctors.	Medical doctor with access to full specialist care.
Facilities available	Stethoscope. BPMD. Thiazides. Optional: Test tubes, holder, burner, solution or test strips for checking urine glucose. Metformin (for refill).	Stethoscope. BPMD. Measuring tape or weighing scale. Test tubes, holder, burner, solution or test strips for checking urine glucose and albumin. Thiazides, beta blockers, ACE inhibitors, calcium channel blockers, (reserpine and methyldopa if the above antihypertensive are not available), aspirin, metformin (for refill).	Stethoscope. BPMD. Measuring tape or weighing scale. Ophthalmoscope. Electrocardiograph. Urine analysis Blood analysis: fasting blood sugar, electrolytes, creatinine, cholesterol and lipoproteins. Thiazides, beta blockers, ace-inhibitors, calcium channel blockers, (reserpine and methyldopa if the above antihypertensive are not available), aspirin, metformin, glibenclamide, insulin, statins and angiotensin receptor blocker (if affordable).
Other facilities	Referral facilities. Maintenance and calibration of BPMDs.	Referral facilities. Maintenance and calibration of BPMDs.	Access to full specialist care. Maintenance and calibration of BPMDs.
Skills of health-care worker (training required for implementing package)	Ability to: • Take relevant history; • Measure blood pressure (systolic only); • Counsel on diet, physical activity and cessation of tobacco use; • Recognize the need for referral; • Prescribe thiazides, oral hypoglycaemic agents (limit to metformin); • Ability to follow-up hypertensives with and without diabetes (availability of necessary drugs, possibility of continuing prescriptions).	Ability to: • Take relevant history; • Measure weight; • Check urine albumen and sugar; • Measure blood pressure; • Diagnose target organ damage and complications of hypertension through history and clinical examination; • Counsel on diet, physical activity and cessation of tobacco use; • Recognize the need for referral; • Manage and follow-up hypertension and follow-up diabetes.	Ability to: • Take relevant history; • Check urine albumen and sugar; • Measure blood pressure; • Diagnose target organ damage and complications of hypertension and diabetes through history and clinical examination; • Record an ECG and read and interpret it; • Counsel on diet, physical activity and cessation of tobacco use; • Link with Scenario 2 for referred patients; • Manage and follow-up hypertension, diabetes and their complications.

graphical areas, the tools of the package may require adaptation to fit local needs.

7.2 What are the characteristics of the package?

Designing an effective package of this nature for less well-resourced settings is a challenging task . To give it a reasonable chance of success, the following features have been incorporated into the package.

Affordability. The package is inexpensive enough for less-affluent patients to access and for less well-resourced public-health systems to sustain.

Acceptability. The tools of the package are based on scientific evidence, and are simple and user friendly so that the package will be satisfactory to individual patients, health-care providers and society at large.

Accessibility. The infrastructure available in most less well-resourced settings will be able to deliver the package .

Applicability. The package is flexible and can be applied in a range of less well-resourced settings, provided there are supportive policy changes and feasible health-system reorganization.

Achievability. The package has been developed to deliver desired results when applied with appropriate changes in policy and health-care organization.

7.3 What are the contents of the package?

The WHO CVD-Risk Management Package consists of a variety of components to guide health-care providers and health systems, even those with minimal resources, to more effective CVD risk management. While the basic elements of the package remain the same across the three scenarios, the specific thresholds for clinical intervention differ across the three resource settings according to the level of available personnel and facilities. The main elements of the package consist of: i) easy-to-follow algorithms for the assessment and management of patients at risk of CVD (risk-assessment and risk-management algorithms; lifestyle counselling protocols; drug treatment protocols; referral pathways and follow-up schedules); ii) tools for both health-care providers and their patients to facilitate implementation of the package (training programme and manual; self-management tools; patient-held records; tools for improving adherence). Community mobilization and participation are essential components for the successful implementation of the package and for the sustainability of the programme.

In collaboration with experts, the package has been developed using an iterative process upon the framework set out by the WHO/International Society of Hypertension evidence-based guidelines for the management of hypertension. The clinical algorithms for risk assessment lead practitioners through pathways of patient characteristics, to stratify each patient's risk profile for CVD. The algorithms then specify appropriate modes of treatment and follow-up for different levels of CVD risk, according to the health-care resources available in a particular setting. Recognizing that the most effective interventions often involve a combined approach, the algorithms involve both nonpharmacological and pharmacological therapies. Drug treatment protocols guide health practitioners to the most appropriate drug classes, while remaining sufficiently flexible so as to encourage the selection of the least expensive generic drug available in the local setting. Lifestyle counselling protocols also aim to be sensitive to the local setting, through local adaptations and an emphasis on pragmatic and simple-to-deliver advice.

The effective management of CVD often requires multiple patient consultations and may require more specialized care if complications

develop. To address these issues, the package includes follow-up schedules that indicate when a patient should return for assessment, with higher-risk patients returning for assessment more frequently. Furthermore, the algorithms explicitly set out the clinical features of patients that require referral to the next level of care. The thresholds for referral differ among the algorithms for the three scenarios, with lower thresholds for referral in settings with the least health resources, and higher thresholds in settings where care may be delivered at the level of a district hospital or similar secondary-care centre.

A major challenge to implementing the package is the current range of skills of the health-care personnel who will be administering the programme. Therefore, a successful package must include a well-designed training programme that imparts an appropriate skill and knowledge base to these individuals and motivates them to see CVD as a key health issue within their communities. The success of the package in achieving its goals, however, depends not only on practitioners delivering the programme, but also includes the patients who are the recipients of the care. Adherence to lifestyle counselling, as well as to the pharmacological therapies proposed in the package, will be a challenge to patients. Monitoring and supporting patient adherence to these new regimens will similarly pose challenges to their health-care providers. These challenges are recognized by the WHO CVD-Risk Management Package through its inclusion of tools for improving adherence. Linked to the idea of patient responsibility for adherence is the concept of self-management, which encourages patients to take a greater role in the process of their treatment and greater responsibility for the outcomes of their care. Patient information cards for wide-scale dissemination and a template for patient-held medical records are included in the package.

7.4 What are the prerequisites for implementing the package?

A basic health-care infrastructure is necessary to apply the CVD risk-management package, to identify people at varying risk levels, and to ensure appropriate treatment of these people. It is important that there are facilities for opportunistic screening of blood pressure, that personnel have been trained to measure blood pressure appropriately, that reliable BPMDs are available, and that ongoing quality control is built into the programme. It is also critical that basic treatment and referral pathways are available for people who are diagnosed as having hypertension and/or diabetes. Again, this requires adequately trained personnel (although these do not have to be qualified physicians) and it also requires a secure supply of appropriate drugs. All these requirements may not be totally fulfilled in all settings and in such situations a concerted effort has to be made to upgrade the existing facilities so that the package can have a maximal impact where applied.

7.5 Next steps

The next steps to promote integrated cardiovascular risk management are being planned, as follows:

Further development, evaluation and implementation of the WHO CVD-Risk-Management Package

The complete package will be developed and refined over the next few months and will contain the following key components:

- A Core Module of easy-to-follow protocols to assist health-care providers assess and manage cardiovascular risk, and counsel on diet, physical activity and cessation of tobacco use in the three scenarios.
- A Training Manual of protocols to assist health-care providers implement the package.

- A Self-Management Module of educational materials and patient self-monitoring protocols, to assist patients and families manage cardiovascular risk.

Before widely implementing the package, it will be tested and evaluated in pilot studies carried out in a range of socioeconomic and cultural settings. The main objective of the pilot studies will be to assess the feasibility and practicability of the package, as initially outlined, and they will be designed as a set of cohort studies, with each implementation site representing one cohort. The studies will be conducted in clinics and will consist of short-term process evaluations. The short-term pilot studies are needed to assess and revise the clinical algorithms and pathways in the package according to early experience, and to gain additional information for the long-term evaluation study.

Subsequently, the effectiveness of the package in reducing cardiovascular events will be evaluated with long-term outcome studies within integrated health systems of defined areas. Long-term outcome evaluation will be done in close collaboration with ministries of health, nongovernmental organizations, media personnel and other stakeholders who would play a central role in advocating the incorporation of the study results into government policy.

Capacity building in countries

To support implementation of the package, WHO plans to collaborate with WHO Regional and Country offices and professional associations to conduct regional training workshops for health-care providers at primary, secondary and tertiary health-care levels.

Advocacy, networking and partnerships

Advocacy material and peer-reviewed publications are being prepared that target medical practitioners, allied health professionals, community-development advocates, health-policy makers and health-care managers. Strategic alliances will be built with a range of international organizations, research and academic institutions, nongovernmental organizations, professional associations and consumer groups to advocate a paradigm shift from a single risk factor intervention, to comprehensive risk profile management.

Development of an accurate and inexpensive BPMD

In collaboration with relevant professional associations and industry, WHO will further explore the development of an accurate and inexpensive BPMD that would be suitable for low-resource settings.

annex

I BPMDs

for low-resource settings

Accuracy is the key criterion in the selection of a BPMD. Other factors include capital and maintenance costs, durability and the amount of training required to use the BPMD. All BPMDs require regular calibration, and the failure to do so has often led to a misdiagnosis of hypertension. At present, manufacturers are not obliged to guarantee the accuracy of their devices, and even though there are more than 500 automatic BPMDs in the market, less than 10% have been independently validated. The accuracy of those that have not been evaluated is questionable and cannot be recommended. There are still examples of manufacturers who continue to market devices that are known to be inaccurate. Purchasers of BPMDs need to check the accuracy and performance of devices in the scientific literature (*www.bmj.com*) and not depend solely on information provided by the manufacturer.

The two most widely-used protocols for evaluation are the British Hypertension Society protocol, and the standard set by the US Association for the Advancement of Medical Instrumentation (*83, 84*). The Working Group on Blood Pressure Monitoring of the European Society of Hypertension recommends evidence-based validation procedures for BPMDs when requested by manufacturers, and if these procedures were to be applied routinely, the results would be a useful guide to purchasers. To expedite validation procedures, the European Society of Hypertension Working Party drafted a simplified international protocol, which will reduce the cost of studies and permit more centres to undertake validation procedures. It is hoped that this will motivate manufacturers to validate devices before they are marketed.

There is the need to explore the possibility of developing an accurate and inexpensive automatic BPMD for worldwide use

Automatic devices eliminate observer bias and all health-care providers, including nonphysician health-care providers, could use them with minimal training. However, issues such as high capital and maintenance cost, or the cost of replacing batteries approximately every 1000 readings, can be problematic in low-resource settings. Currently, the only data for comparing the durability, running costs and suitability for low-resource settings of the automatic and conventional devices are provided by manufacturers.

Mercury sphygmomanometers are reasonably accurate, but like all sphygmomanometers, they need regular servicing. If blood pressure is being measured with a mercury sphygmomanometer the observer has to be trained in the auscultatory technique of blood pressure measurement and assessed for accuracy in the technique; all too often training and assessment is taken for granted. Even with observer training, observer error, observer bias and terminal digit preference often cause the technique to be inaccurate. It needs to be borne in mind that a good quality stethoscope is essential for recording the Korotkoff sounds using the auscultatory technique and this can add substantially to the basic cost. If resources are very limited, a compromise solution might be to train observers to measure systolic blood pressure at the wrist by palpation only.

Due to issues of environmental toxicity of mercury some European countries have banned mercury and others, such as the UK, are recommending that mercury sphygmomanometers should not be replaced. In settings where it is considered necessary to continue to use mercury sphygmomanometers special precautions have to be taken in servicing them, in avoiding mercury spills and in ensuring the safe disposal of nonfunctioning devices.

Aneroid devices are cheap and portable, but users need to be trained in the auscultatory technique. As with the mercury sphygmomanometer, this technique can give rise to observer error, observer bias and terminal digit preference. The aneroid sphygmomanometers also become inaccurate with use, without this being apparent to the user, and they need to be calibrated every six months.

Regardless of the type of sphygmomanometer used – mercury, aneroid or automated – the inflatable bladder has to be selected to suit the circumference of the arm in which blood pressure is being measured. Inappropriately small bladders will give falsely high readings, and inappropriately large bladders will give falsely low blood pressures. The width of the bladder should be 40% of the arm circumference and the length of the bladder should encircle at least 80% of the arm.

Recommendations on BPMDs

I. When it is not feasible to use validated automatic devices, good quality mercury devices are generally recommended. Provision should be made to service and calibrate the devices once a year. Appropriate cuff sizes and adequate training of users are critical to ensure accurate blood pressure measurement. Due precautions need to be taken when servicing and disposing of devices because of mercury toxicity, and the necessary precautions for dealing with mercury spills should be available.

II. Automated devices should only be used if independently validated devices are available at affordable prices. When making a decision as to whether to use automated devices, consideration must be given to the cost and availability of batteries, annual servicing charges and durability, in addition to the purchase price of the device.

III. In certain settings, aneroid devices may have to be used as they are the least expensive and easily portable. However, they may become inaccurate without the user being aware of it and require calibration every six months. Adequate training of users is critical to ensure accurate blood pressure measurement.

IV. WHO, together with relevant partners and in collaboration with industry, needs to explore the possibility of developing an accurate and inexpensive automatic BPMD for worldwide use.

V. WHO needs to initiate comparative studies to investigate the impact of different categories of BPMDs on the accuracy of diagnoses and on the management of hypertension.

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