Pharmacy-Based Hypertension Management Model: Protocol and Guidelines

A joint CINDI/EuroPharm Forum project
1. Introduction

This document was produced by EuroPharm Forum and the WHO CINDI Programme in order to improve hypertension control at the community level. It is mainly addressed to community pharmacists. The document should be used as a guide when organizing pharmacy-based work within hypertension management. However, it can also be used by individual health professionals interested in this type of work.

The document consists of the following parts:
- background information including the development of this project;
- partnership and the involvement of pharmacists;
- the pharmacy-based hypertension management model including the objectives, target population, intervention strategies as well as documentation and evaluation of process and outcomes;
- the organizational structure of the project;
- guidance on training and preparatory work;
- guidance for pharmacists on how to implement a hypertension management service.

Checklists and forms are attached to facilitate work at local level.

2. Background information

2.1. Rationale

Hypertension remains a major health problem in most countries because of its impact on the population attributable mortality and morbidity due to insufficient hypertension prevention and control at community level.

Indeed, hypertension accounts for more than 5.8% of total deaths, 1.9% of years of life lost and 1.4% disability adjusted life years all over the world. These figures are more dramatic in the formerly socialist economies countries (1).

Concerning hypertension control, blood pressure is under control in less than 20% of patients with hypertension in many countries. This is mainly because hypertension often remains undetected, although easy to diagnose. Even though hypertension may be simple to treat, it very often remains untreated. Despite the availability of useful non-drug therapy and potent medications, treatment is too often ineffective, mainly as a consequence of the lack of patient’s compliance with therapeutic regimens.

Therefore, hypertension prevention and control in the community is currently a pivotal challenge. This largely justifies the implementation of a set of interventions mainly focused on:
• development and implementation of standardized health information systems;
• development of integrated interventions based on interdisciplinary and intersectorial collaboration;
• intensified public health education;
• continuing education programmes for health professionals;
• improved hypertension management practices.

2.2. The CINDI initiative

The Action Plan of the WHO CINDI (Countrywide Integrated Noncommunicable Diseases Intervention) Programme aims to realize the potential for prevention of noncommunicable disease (NCD) through the prevention and control of major risk factors common to NCD through community based interventions and through primary health care systems (2). To strengthen collaboration among health professionals in the implementation of a balanced health promotion and disease prevention the CINDI programme initiated collaboration with EuroPharm Forum. The idea was to involve pharmacists actively in the prevention and control of major risk factors such as hypertension, obesity and smoking.

In 1995 a plan for collaboration was outlined. The plan included the development of a project on noncommunicable disease prevention, focusing on hypertension control. A draft project proposal on developing a pharmacy-based hypertension management model was presented to the EuroPharm Forum and the Forum established a task force comprising 14 countries. Networks of family physicians and pharmacists working on the primary prevention of NCD with focus on hypertension have been established in a number of countries.

2.3. Development of a collaborative project

In 1997, a joint meeting of the CINDI Working Group on Hypertension and the EuroPharm Forum was organized (3). It was aimed to share the first practical experiences of involving pharmacists in hypertension, prevention and control and to draw up the basis for a collaborative project.

It was agreed that the main goal of the project would be to improve hypertension control at community level through the more active involvement of pharmacists in the prevention, detection and management of hypertension. The intervention strategies would be the following:

• health education
• screening for risk factors
• counselling
• blood pressure measurement
• training in self-measurement of blood pressure.

A draft project proposal on a pharmacy-based hypertension management model including a draft structure of the project protocol was discussed. It was recommended to start developing an international project protocol and guidelines for implementation.
3. Partnership in hypertension management

A recent CINDI survey (4) identified that lifestyle modifications and better patient compliance with antihypertensive medication ought to be priority issues in hypertension management. This calls for a more active role of primary health care and for multidisciplinary collaboration. Multidisciplinary collaboration means concerted action among various partners of both health and non-health sectors.

Partnership is a fundamental strategy of multidisciplinary collaboration. Within the framework of multidisciplinary collaboration the partners have different opportunities to identify and solve problems. The sharing of information between partners is beneficial to all involved and is likely to contribute to care, the continuity of which relies on effective movement of this shared information across disciplines and on follow-up.

In the field of hypertension management a GP is the key partner for a patient in primary health care. Patients are both beneficiaries and team members. Sharing information and expectations with the patient in the team is a way of achieving patient concordance and successful hypertension management.

Pharmaceutical care is an example of a patient care system depending on partnership and a team approach. The Pharmaceutical Care concept is defined as: the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life (5). This practice is delivered when an assessment is performed, a care plan developed, and a follow-up evaluation is completed for a patient at each visit at the pharmacy. The assessment consists of a systematic medication review by the pharmacist to identify drug related problems and other health problems. The next step – the care plan – consists of a definition of patient goals in collaboration with the GP and the pharmacist’s intervention to resolve possible problems by reinforcing compliance and reporting drug problems to the GP that may require drug therapy adjustments. The follow-up evaluation consists of an evaluation of patient’s progress toward goals at planned intervals of follow-up, as according to information received from the GP (6).

In other words, pharmaceutical care is a patient care system that continually observes the short-term results of the therapy in progress and helps to make corrections to improve management outcomes. The concept requires a multidisciplinary approach and the team would normally consist of a patient, a GP, a pharmacist and a nurse.

4. Why should pharmacists be involved in hypertension management

4.1. Advantages

More than 20 million people visit a pharmacy every day in Europe. A community pharmacist is a highly trained professional who can be seen without appointment, in an informal setting which is often considered to be part of an every day shopping experience. Pharmacists are therefore the most highly accessible members of the primary health care team. Community pharmacies are visited by both people who are sick and people who are in good health. Therefore community pharmacies have a potential for health promotion and disease prevention. Regular visits of a person with hypertension for prescribed drug therapy puts the patient in a regular contact with the pharmacist and provides opportunities for intervention. The pharmacist can complement the
GP in hypertension management in various ways (7–10). The following are examples of such opportunities where pharmacists participate with other health care professionals in community based health promotion and disease prevention and management programmes.

- Pharmacists have an extensive knowledge about the principles of drug therapy, use of medicines and prevention.
- Pharmacists can verify and improve the patients’ knowledge about necessary lifestyle modifications and the use of medicines and improve compliance with therapy.
- Pharmacists can identify drug therapy related problems and recommend possible solutions including referrals to the GP.
- Pharmacists can monitor therapeutic outcomes of hypertension management.

4.2. Adherence to long-term therapies

Pharmaceutical care is an effective approach to improving adherence to long-term therapies. Advice, information and referral by community pharmacists have been demonstrated to significantly improve adherence to antihypertensive therapy and improve blood pressure control (10).

Pharmacists are also involved in giving information and service to patients with hypertension. It has been shown that after having provided appropriate health education and monitoring services to patients with hypertension, primary care pharmacists managed to get patients to use less expensive antihypertensive medication (11). Patients with hypertension received pharmaceutical care from community pharmacies comprehending education, assistance to reach compliance and recommendations to their GPs regarding drug therapy. In several studies the intervention group showed a significant decrease in mean blood pressure (12–16).

The involvement of pharmacists in hypertension management falls in line with the Good Pharmacy Practice document developed and adopted in 1994 by the Pharmaceutical Group of the European Union (PGEU). It represents the first set of standards for pharmacy practice developed by the Profession (17) and with the international standard for Good Pharmacy Practice (GPP) in Community and Hospital Pharmacy Setting developed by WHO (18). The first element of Good Pharmacy Practice is Health Promotion and Ill-health Prevention, and according to the document a number of national standards have to be elaborated within this area.

Currently, new programmes involving community pharmacies in Good Pharmacy Practice programmes or pharmaceutical care programmes are being developed and introduced. Some midterm results from Portugal (19), Spain (20) and United Kingdom (21) show that community pharmacists are capable of providing pharmaceutical care leading to good results with regards to optimizing the drug therapy and achieving more cost-effective outputs.

5. The Pharmacy-based hypertension management model

5.1. Objectives

The main goal is to improve hypertension control at community level through a more active involvement of pharmacists in the prevention, detection and management of hypertension.
The **operational goal** is to establish a pharmacy-based hypertension management model.

The **evaluation goal** is to document the output and to monitor and assess outcomes of a pharmacy-based hypertension management model.

### 5.2. Target population

The target population is the pharmacy customers with special focus on:

- those being treated for hypertension;
- those with unfavourable CVD risk profile (e.g. smokers, overweight persons, persons with diabetes and/or high level of cholesterol), who might have unidentified high blood pressure.

However, any adult pharmacy customer may be counselled on health promotion and disease prevention.

### 5.3. Description of the model

The proposed model is intended for use in any country. As each country has different local settings and structures, population health status and priorities and available resources and skills, a uniform model is not applicable. In order to make the protocol suitable in various countries three different levels of intervention strategies are proposed. These three levels (listed below) do not appear in any order of importance or order of progression. Situations differ between countries, and priorities regarding the implementation of the three types of intervention will be set at local level. The model is thoroughly described in the Guidelines.

Certain requirements have to be met by the pharmacies implementing the project. The staff must be trained and relevant information material must be available. It would be an advantage if the pharmacy could set up audiovisual equipment to improve health education of the customer. It is recommended that the pharmacy has a special area for ensuring privacy.

If level two and three of intervention strategies are implemented, it is necessary to provide the necessary training of pharmacists and calibrate the equipment for blood pressure measurement.

### 5.3.1. Level one: Primary prevention

**Goal:**

- to promote healthy lifestyle for CVD prevention through health education.

At this level advice on healthy lifestyles is given to pharmacy customers, in particular to adult individuals with unfavourable cardiovascular risk profile.

The pharmacy customer counselling comprises lifestyle modifications, e.g. healthy diet, adequate physical activity and stopping smoking.
5.3.2. Level two: Detection

Goal:

- to contribute to early detection of hypertension by measuring blood pressure of a customer and referring possible persons with possible hypertension to the GP. Simultaneous screening for other cardiovascular risk factors can be provided.

5.3.3. Level three: Management of hypertensive patients on treatment

Goals:

- to monitor patients with hypertension on treatment and to refer to the GP those who do not achieve an adequate blood pressure control;
- to identify possible drug related problems and report them to the GP;
- to obtain and reinforce informed compliance;
- to provide health education to patients with hypertension about necessary lifestyle modifications;
- to advise on treatment regimen to patients with hypertension;
- to teach about self-measurement of blood pressure.

Level three contributes to the monitoring of patients with hypertension on treatment.

It is particularly important that the pharmacist follows-up on the patient’s blood pressure and compliance to treatment in between the patient’s visits to the GP, since it complements the GP’s role and helps to ensure therapeutic compliance.

The monitoring of patients with hypertension on treatment comprises:

- regular blood pressure measurement;
- patient counselling and information on drug treatment (use of medicines, possible side effects, interactions with other drugs and contraindications);
- monitoring of patient health problems, preferences and beliefs;
- reporting possible drug related problems to the GP;
- measuring informed therapeutic compliance;
- counselling on lifestyle modifications;
- teaching of self-measurement of blood pressure and its recording in a diary.
Examples of goals to be achieved at each level:

<table>
<thead>
<tr>
<th>Level</th>
<th>Main goal</th>
<th>Operational goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Active involvement of pharmacists in primary prevention of hypertension.</td>
<td>Availability of educational materials about primary prevention of hypertension (healthy diet, appropriate physical activity, prevention of smoking, stress management etc.).</td>
</tr>
<tr>
<td>Level 2</td>
<td>Active involvement of pharmacists in the early detection of hypertension.</td>
<td>Availability of pharmacists-GPs referral protocols.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implementation of continuing pharmacists’ education programmes about blood pressure measurement including self-measurement.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Availability of a calibration system for blood pressure measurement devices.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Active involvement of pharmacists in the improvement of informed therapeutic compliance of treated customers with hypertension.</td>
<td>Implementation of coordination systems between pharmacists and other health professionals.</td>
</tr>
<tr>
<td></td>
<td>Active involvement of pharmacist in the promotion and adequate management of self measurement of blood pressure.</td>
<td>Implementation of continuing pharmacist education programmes about blood pressure measurement.</td>
</tr>
<tr>
<td></td>
<td>Active involvement of pharmacists in life-long blood pressure control of treated patients with hypertension.</td>
<td>Implementation of patient education programmes on self-measurement of blood pressure.</td>
</tr>
<tr>
<td></td>
<td>Active involvement of pharmacists in preventive activities related to other cardiovascular risk factors, namely dyslipidaemia, diabetes, smoking, obesity, sedentarism, psychosocial stress.</td>
<td>Implementation of continuing pharmacist education programmes about improving informed therapeutic compliance in patients with hypertension on treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implementation of continuing pharmacist education programmes about prevention and control of other cardiovascular risk factors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Availability of pharmacist protocols for management of patients with hypertension.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Availability of a calibration system for devices of blood pressure measurement.</td>
</tr>
</tbody>
</table>

5.4. Documentation and evaluation

All pharmacists are encouraged to set up evaluation as part of the implementation of pharmacy-based hypertension management. By evaluating the appropriateness of the model training can be judged and the value of the involvement of pharmacists in hypertension management can be documented.

To assess the extent to which the programme has attained the proposed objectives, several indicators have been proposed (see Chapter 9). General epidemiological indicators such as stroke, mortality rate and hypertension detection, treatment and control rates are not feasible for measuring at pharmacy level and therefore not included in the protocol.
The documentation and evaluation of the project is thoroughly described in the Guidelines for pharmacists. Examples of the indicators are in Chapter 9.9.

The pharmacy should keep a log over activities connected with the project. The log is divided into three levels. In the log the pharmacist should register the indicators.

It is recommended to carry out ad hoc surveys about health professionals and pharmacy customers’ satisfaction.

6. Organizational structure of the project

Successful implementation of the project requires that appropriate organizational structure be established.

It is recommended that the collaboration between pharmacists and GPs be established at international, national and local level with well defined tasks.

**International level**

EuroPharm Forum has appointed a Task Force Manager for the project and a CINDI/EuroPharm Forum Steering Committee has been established in order to ensure the preparation and co-ordination of the international project together with effective fund-raising.

On the basis of this protocol the Task Force Manager should:

1. make a strategy for the implementation for the Task Force Members in the International Task Force;
2. manage feedback of core data and national experiences;
3. create and manage information about the international CINDI Pharmacy-based hypertension management programme.

**National level**

Pharmaceutical associations interested in participating in the project have to appoint a Task Force Member to start the project in their country. Contacts with the national CINDI team and with relevant patients associations should be established.

The Task Force Member and the pharmaceutical association(s) in cooperation should establish a National Task Force, which would be responsible for the project at national level. The National Task Force should:

1. identify suitable areas for pilot studies, if pilot studies are necessary
2. provide educational materials
3. draft the project manual for the pharmacies
4. run training courses for pharmacists
5. coordinate the project implementation in participating pharmacies
6. collect data from the participating pharmacies
7. analyze project implementation results
8. provide results to the EuroPharm Forum/CINDI Task Force Manager.

**Local level – pharmacy level**

The pharmacies which have been chosen for the project should:

1. establish a local task force, if convenient;
2. adjust the project protocol and the pharmacy manual to local conditions in consultation with the National Task Force;
3. elaborate an action plan for the implementation of the project in cooperation with the National Task Force;
4. implement the project;
5. collect data from the project;
6. give the National Task Force feedback on local experiences and the data from the project.

It is recommended to establish a local contact group in support of the project. A contact group could consist of representatives from the patient association (if any), the GP’s and other relevant health care representatives.

**7. Ethical aspects**

In many countries it is necessary to obtain approval from the Ethical Committee if the project is implemented as a research project. The National Task Force is responsible for obtaining approval and should also make sure if other national approvals are required for a project of this kind.

In some countries it is only permitted to keep patient files if the patient has given written informed consent. The National Task Force is responsible for the necessary procedures.

**8. Training and preparatory work**

To facilitate the implementation of the hypertension management model it is recommended to elaborate and run special training programmes. Training courses should be offered to pharmacists and skilled staff (if convenient) of the participating pharmacies at national and local level. The national programme should be supported by the pharmaceutical association(s). It is recommended to organize local training seminars for small groups and ask the local health professionals to participate.

The training programme should be based on the guidelines on how to run a pharmacy-based hypertension management model and cover the topics outlined below:

- introduction to cardiovascular disease;
- hypertension;
- antihypertensive medication: types of medication used to control hypertension and their effects, side effects, contraindications etc.;
• how to improve informed compliance;
• communication skills and patient education;
• primary prevention of hypertension (lifestyle modifications);
• techniques for measuring blood pressure;
• pharmaceutical care;
• registration forms for evaluation purposes;
• links between pharmacist and the national association including agreement forms;
• levels of responsibility of pharmacists and staff at the pharmacy.

The training course should also include case studies, practical training in blood pressure measurement, patient education and recommendations for calibration of the device for blood pressure measurement.

At the seminar the pharmacists should get written information about:
• methods for blood pressure measurement
• validation and calibration of devices for blood pressure measurement
• hypertension (material produced for the training course).

Preparatory work includes making project material available. Before implementing the project pharmacies should be provided with project material:
• information material to promote screening activities in pharmacy windows;
• information material (i.e. press releases) to promote the activity;
• leaflets to give information about hypertension and cardiovascular diseases;
• leaflets to give information about lifestyle modifications and antihypertensive medication;
• pharmacy manual;
• forms for documentation;
• information material for customers/patients with hypertension on the following topics:
  – hypertension
  – healthy diet
  – physical activity
  – smoking cessation
  – reduction in alcohol consumption
  – coping with stress.

Furthermore it is recommended to establish a reference calibration centre at local level.
9. Guidelines for the implementation of the pharmacy-based hypertension management model

9.1. Introduction

These guidelines outline various ways in which pharmacists can participate in the pharmacy-based hypertension management model, obviously in close cooperation with the GP. There are three levels of intervention strategies which are in line with different levels of time commitment from the pharmacist and trained staff, so that, depending on national or individual plans, pharmacists can choose which level(s) of intervention (service) they are able to provide.

These guidelines aim to be of practical use and include some useful tools for the community pharmacist, such as:

- checklists of certain aspects that should not be forgotten when providing a hypertension management service;
- protocols designed to harmonize procedures at the pharmacy;
- forms to be filled at the pharmacy (can be adapted to pharmacy computerized databases);
- recommended action for the pharmacist.

We draw your attention for the need to fill in the forms available, in order to record all steps taken when providing a pharmacy-based hypertension management service. Remember this valuable data will be the only source of information available to assess the impact of pharmacists’ action in a hypertension management service.

We have taken into account the usual limited amount of time available when dispensing in a pharmacy and, therefore, the forms are not extensive, in order to encourage data storage and recording.

All these tools are just guidelines for intervention strategies which should, naturally, be adjusted to each country’s own reality, both at national and local levels.

National pharmaceutical associations of member countries are, therefore, free to use these guidelines or adapt them for implementation in their own countries.

9.2. Level 1 – Primary prevention

Goal:
- to promote healthy lifestyle for CVD prevention through health education.

This level is designed for pharmacists and trained staff to advise pharmacy customers and, in particular, the adult individuals most at risk to adopt healthier lifestyles in order to prevent high blood pressure and associated cardiovascular diseases.
There is general consensus on the modifiable risk factors of elevated blood pressure:

1. excessive intake of calories
2. high intake of salt
3. excessive intake of alcohol
4. inadequate physical activity
5. smoking
6. high intake of saturated fatty acids
7. regular use of contraceptives.

Psychosocial stress seems to be another risk factor of high blood pressure.

Gradient of risk for CVDs increases with the increase of risk factors in an individual. Based on this evidence, a lifestyle modification for hypertension control requires management of overall cardiovascular risk profile. The strategies have been clearly identified: to lose weight if overweight; to limit alcohol intake; to increase physical activity on a regular basis; to reduce salt intake; to maintain adequate fruits and vegetables intake; to stop smoking and to control fat intake.

These measures are used for four complementary reasons:

- to lower blood pressure in an individual patient
- to reduce the need for antihypertensive medicines
- to minimize associated risk factors in an individual
- to prevent hypertension and associated CVDs.

They reduce the profile of risk factor for atherosclerosis and may improve overall health.

Advice should be given verbally and may be completed with written information such as leaflets, flyers or through posters/videos displayed in the pharmacy.

9.3. Level 2 – Detection

Goal:

- to contribute to early detection of hypertension by measuring blood pressure of a customer and referring possible persons with possible hypertension to the GP. Simultaneous screening for other cardiovascular risk factors can be provided.

The detection consists of:

- blood pressure measurement and assessment
- possible screening for other risk factors.
Operational classification of hypertension by blood pressure level*

Normal blood pressure for adults is defined as systolic blood pressure below 140 mmHg and diastolic blood pressure below 90 mmHg. However, it should be stressed that when managing hypertension all cardiovascular risk factors should be assessed and controlled, if necessary.

<table>
<thead>
<tr>
<th>Category</th>
<th>Systolic blood pressure (mmHg)</th>
<th>Diastolic blood pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimal</td>
<td>&lt; 120</td>
<td>&lt; 80</td>
</tr>
<tr>
<td>Normal</td>
<td>&lt; 130</td>
<td>&lt; 85</td>
</tr>
<tr>
<td>High-normal</td>
<td>130–139</td>
<td>85–89</td>
</tr>
<tr>
<td>Grade 1 hypertension (mild)</td>
<td>140–159</td>
<td>90–99</td>
</tr>
<tr>
<td>Subgroup: borderline</td>
<td>140–149</td>
<td>90–94</td>
</tr>
<tr>
<td>Grade 2 hypertension (moderate)</td>
<td>160–179</td>
<td>100–109</td>
</tr>
<tr>
<td>Grade 3 hypertension (severe)</td>
<td>≥ 180</td>
<td>≥ 110</td>
</tr>
<tr>
<td>Isolated systolic hypertension</td>
<td>≥ 140</td>
<td>&lt; 90</td>
</tr>
<tr>
<td>Subgroup: borderline</td>
<td>140–149</td>
<td>&lt; 90</td>
</tr>
</tbody>
</table>

Source: reference 29

Hypertension may also be classified by extent of organ damage and aetiology which, however, are beyond the scope of this document since they imply a clear diagnosis of the patient and are, hence, restricted to the boundaries of the medical profession. However, organ damage and aetiology are important with regard to future complications that may arise. This reinforces the need for a close cooperation between health professionals.

**Blood pressure measurement**

Obtaining an accurate blood pressure measurement is important in any situation. Mercury or aneroid sphygmomanometers or automated devices for blood pressure measurement are available. When using automated devices it is recommended to choose exclusively the internationally validated ones (see table I) and they must be periodically calibrated. It should be noted that aneroid devices could become inaccurate without the person measuring blood pressure noticing that.

Blood pressure measurement should be performed according to the recommendations listed in these Guidelines.

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*This classification was defined by WHO/ISH in 1999 (29) and follows in principle the definition and classification provided in 1997 in the 6th Report of the Joint National Committee. It has also been adopted by the ESH/ESC in 2003 (30) for the management of patients with hypertension. This blood pressure levels should be complemented with the global cardiovascular risk profile as stated in the 1999 WHO/ISH guidelines (29) and in the 2003 WHO/ISH Statement (31). The above table provides the classification of blood pressure levels in adults over the age of 18. Hypertension is defined as a systolic blood pressure of 140 mmHg or higher and/or a diastolic blood pressure of 90 mmHg or higher in subjects who are not taking antihypertensive medication.
9.4. Level 3 – Management of patients with hypertension on treatment

Goals:
- to monitor patients with hypertension on treatment and to refer to the GP those who do not achieve an adequate blood pressure control;
- to identify possible drug related problems and report them to the GP;
- to obtain and reinforce informed compliance;
- to provide health education to patients with hypertension about necessary lifestyle modifications;
- to advise on treatment regimen to patients with hypertension;
- to teach about self-measurement of blood pressure.

This model implies that at this level, pharmacists monitor patients with hypertension on the non-drug/drug treatment prescribed by the physician. The follow-up of such patients by the pharmacist is particularly important between the patient’s visits to the doctor, since it complements the doctor’s role and helps to ensure therapeutic compliance.

Follow-up of patients with hypertension at the pharmacy should include:
- regular blood pressure measurement and other relevant health parameters
- patient counselling and information on treatment
- reinforcement of therapeutic compliance
- identification of possible drug related problems and report to the GP
- counselling on lifestyle modifications
- patient counselling and information on self-medication
- teaching self-measurement of blood pressure.

9.4.1. Patient counselling and information on drug treatment

There is evidence that early treatment may reduce the likelihood of developing more severe hypertension at a later time, hence reducing cardiovascular morbidity and mortality. The lower the blood pressure, the lower the risk of both stroke and coronary events.

Pharmacists should inform patients with hypertension on relevant aspects related to drug treatment (medicine(s) taken, dosage regimen, possible side effects, interactions and contraindications).

The following six classes of antihypertensive agents are more commonly prescribed for the first-line treatment of patients with hypertension:
- thiazide diuretics
- β-blockers
- calcium channel blockers
- angiotensin converting enzyme (ACE) inhibitors
- angiotensin II receptor blockers
- α-blockers.
9.4.2. Reinforcement of compliance

Compliance with a prescribed non-drug/drug treatment is a long-term, usually permanent issue, requiring ongoing educational efforts from pharmacists as a complement to medical advice.

Full information should be given to patients with hypertension on treatment. The following points should be particularly emphasized:

- blood pressure goals and benefits for patient resulting from optimal control
- the frequent lack of symptoms of hypertension
- the reasons for treatment
- possible side effects of drug treatment
- the need for continuous (usually lifetime) treatment and extended follow-up
- the risk of complications if compliance with treatment fails.

Patients should also be aware that lifestyle measures, even in patients on drug treatment, are of paramount importance and enable the use of fewer medicines in lower doses, hence reducing side effects.

Self-measurement of blood pressure may be helpful to ensure the patient compliance with the treatment for certain patients. Pharmacists may help patients choose the most adequate device for self-measurement and its correct use.

Patient education makes a significant contribution to positive patient outcomes.

9.4.3. Patient counselling and information on self-medication

Pharmacists should discourage patients with hypertension to take certain medicines capable of inducing hypertension, without medical or pharmaceutical advice:

- oral corticosteroids
- non-steroidal anti-inflammatory drugs (NSAIDs)
- oral and nasal decongestants
- oral contraceptives
- amphetamines
- liquorice
- bicarbonate.

9.4.4. Teaching of self-measurement

The modern concept of health promotion and disease prevention determines patient’s empowerment. In fact, self-measurement of blood pressure, as a complement to health professionals blood pressure assessment, is a powerful strategy to improve compliance and it encourages patients to have a more active role in blood pressure overall management. This has the advantage of providing more frequent measurements, which are also taken in a more relaxed setting. It is known that the presence of health professionals may cause some emotional rise in blood pressure (“white-coat effect”).
• Pharmacists and patients should be aware that home blood pressure readings are on average lower than values recorded by health professionals.

• Self-measurement of blood pressure is a simple and economic tool to obtaining a blood pressure profile. However, patients and relatives should receive appropriate instructions and training in order to ensure reliable measurements. Blood pressure measurement should be performed according to the recommendations listed in these Guidelines.

• Patients with mild and moderate hypertension should be given a patient card, in which blood pressure measurements from all sources and changes of drug treatment, when existing, may be recorded. After a time this diary becomes a valuable record of blood pressure trends and can be presented to the pharmacist. The same card should be presented to the GP, in case of referral or previously set appointment. In routine practice a twice daily measurement of blood pressure twice a week, depending on the severity of hypertension, will give a reasonable indication to both the patient and pharmacist of blood pressure control. Once the level of blood pressure is controlled, a once-a-month measurement may be sufficient.
Table 1. List of validated blood pressure devices according to the Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS) (Updated December 2002) that could be used for self-measurement of blood pressure

<table>
<thead>
<tr>
<th>METHOD</th>
<th>MODEL</th>
<th>AAMI STANDARDS</th>
<th>BHS STANDARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oscilometric</td>
<td>UA 751</td>
<td>Yes</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>HP5306/B (Philips)</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td></td>
<td>HP 5332 (Philips)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Healthcheck CX-5 060020</td>
<td>No</td>
<td>No</td>
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<tr>
<td></td>
<td>Dr MI-100 (Fortec)</td>
<td>No</td>
<td>No</td>
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<td></td>
<td>Dr MI-150 (Systema)</td>
<td>No</td>
<td>No</td>
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<tr>
<td></td>
<td>HEM 403C (Omron)</td>
<td>No</td>
<td>Yes</td>
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<td></td>
<td>HEM 637 IT (Omron)</td>
<td>Yes</td>
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<td></td>
<td>HEM 700 C (Omron)</td>
<td>Yes</td>
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<td></td>
<td>HEM 706 (Omron)</td>
<td>Yes</td>
<td>Yes</td>
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<td></td>
<td>HEM 705 CP (Omron)</td>
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<td>Yes</td>
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<td></td>
<td>HEM 705 IT (Omron)</td>
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<td>Yes</td>
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<td>HEM 703CP (Omron)</td>
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<td>HEM 711 (Omron)</td>
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<td>HEM 713C (Omron)</td>
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<td>HEM 722C (Omron)</td>
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<td>HEM 735C (Omron)</td>
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<td>HEM 737 Intellisense (Omron)</td>
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<td>HEM 773 (Omron)</td>
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<tr>
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<td>HEM 907/907-E (Omron)</td>
<td>Yes</td>
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<tr>
<td></td>
<td>M1 (Omron)/HEM 422C2-E</td>
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<tr>
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<td>M4 (Omron)/HEM 722C1-E</td>
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<td>MX2 (Omron)/HEM 732-E</td>
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<td></td>
<td>M4 I (Omron)/HEM 752A-E</td>
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<td></td>
<td>M5 I (Omron)/HEM 757A-E</td>
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<td></td>
<td>Nissei DS-175</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td></td>
<td>OZ2 (Visomat)</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Auscultatory</td>
<td>Nissei analogue monitor</td>
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<td>DS-40 (Nissei)</td>
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<td></td>
<td>DS-55 P (Nissei)</td>
<td>Yes</td>
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<td>Tycos</td>
<td>Yes</td>
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<td>HP5308 (Philips)</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Aneroid</td>
<td>Cuffed (Nissei)</td>
<td>Yes</td>
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<td>Erka (Bad Tolz)</td>
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<td>Accoson (Cossa)</td>
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<tr>
<td>Wrist</td>
<td>R1 (Omron)/HEM 601-E</td>
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<td>R3 (Omron)/HEM 605-E</td>
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<td>RX (Omron)/HEM 608-E</td>
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<td>RX-M (Omron)/HEM 628</td>
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<td>R5 I (Omron)/HEM 630-E</td>
<td>Yes</td>
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<td></td>
<td>RX I (Omron)/HEM 632-E</td>
<td>Yes</td>
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<td></td>
<td>Boso-Mediwatch</td>
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<tr>
<td>Finger</td>
<td>No one</td>
<td>No one</td>
<td>No one</td>
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</tbody>
</table>

Source: reference 28
9.5. Checklist for lifestyle measures that contribute to lowering blood pressure

- **Weight reduction**
  Body Mass Index (BMI) should be lower than 25 kg/m$^2$.

  \[
  \text{BMI} = \frac{\text{Weight in Kg}}{\text{Height in m}^2}
  \]

  Overweight/obese individuals (BMI over 25) should be encouraged to set a long-term target for weight loss at a slow and gradual rate. Severely obese patients (BMI over 37) should be encouraged to consult a specialist.

  The importance of healthy eating and physical activity should be emphasized to maintain weight after a satisfactory level has been achieved.

- **Healthy diet**
  - **Reduction of salt intake.** It should be limited to a maximum of 6 g/day. In practice, individuals should avoid salted, cured, pickled, processed and smoked food and not add salt to food when or after cooking.
  - **Reduction of alcohol intake.** If alcohol is consumed, its intake should be limited to no more than two drinks (each containing 10 g alcohol) per day, (20 g is approximately equivalent to 2 small glasses of wine, a pint of beer or 2 measures of spirits (whisky, brandy or vodka)).
  - **Control of fat intake.** Fat intake should be limited to not more than 30% of daily energy and most saturated fats should be replaced with unsaturated vegetable oils or soft margarines.
  - **Sufficient consumption of fruits and vegetables.** It is recommended to eat a variety of fruits and vegetables several times per day (at least 400 g per day).

- **Regular physical activity**
  - Dynamic isotonic exercise (brisk walking, swimming, cycling, running, rowing, step climbing, hiking) is recommended on a regular basis (3–4 times a week; 30–45 min per day) depending on each individual and initial level of fitness.
  - Isometric exercise such as heavy weight lifting should be avoided.
  - Patients with health problems including individuals with years of sedentarism should first get advice from a doctor.
  - Verbal advice given on lifestyle modifications should be enforced by written information (e.g. leaflets, articles for the public, etc).

- **Smoking cessation.** This is perhaps the single most powerful lifestyle measure for the prevention of both cardiovascular and noncardiovascular diseases in hypertensive patients. All hypertensive patients who smoke should receive appropriate counselling and assistance for smoking cessation and drug treatment when needed (nicotine replacement, bupropion).

- **Control of diabetes** (under medical surveillance).

Source: Adapted from references 22–27, 29–32.
9.6. Protocol for the procedure of blood pressure measurement common to all devices (mercury/aneroid sphygmomanometers and automatic devices)

An accurate and validated device must be used for blood pressure measurement.

a. The procedure

a.1. Explanation to the individual
   The first step in blood pressure measurement is adequate explanation of the procedure. Those having blood pressure measured for the first time should be told that there is minor discomfort caused by inflation of the cuff.

a.2. Patient education
   Illustrated instruction materials are helpful in this context.

a.3. Attitude of observer
   Before taking the blood pressure, the observer should be in a comfortable and relaxed position, and should not rush the procedure, otherwise the cuff may be deflated too rapidly. If any interruption occurs, the exact measurement may be forgotten and an approximation made. The blood pressure should always be documented as soon as it has been measured.

a.4. Attitude of patient
   Patients should be encouraged to relax and be advised that neither they nor the observer should talk for the few minutes before or during the blood pressure measurement.

a.5. Position of the patient.
   Blood pressure is usually measured with the individual in the sitting position. 5 min is suggested to rest before blood pressure measurement is taken.

a.6. Arm support
   It is essential, for the arm to be supported during blood pressure measurement,

a.7. Arm position
   The forearm must be at the level of the heart as denoted by the mid-sternal level.

a.8. Which arm?
   Bilateral measurement should be made on first consultation and, if reproducible differences greater than 20 mmHg for systolic or 10 mmHg for diastolic pressure are present on consecutive readings, the patient should be referred for further evaluation.

a.9. The cuff and bladder
   Tapering cuffs should be long enough to encircle the arm several times: the full length should extend beyond the end of the inflatable bladder for 25 cm and then should gradually taper for a further 60 cm. Velcro surfaces must be effective, and when they lose their grip the cuff should be discarded. It should be possible to remove the bladder from the cuff so that the latter can be washed from time to time.

a.9.1. “Cuff hypertension”
   There is unequivocal evidence that either too narrow or too short a bladder (under cuffing) will cause overestimation of blood pressure – so called “cuff hypertension” – and there is growing evidence that too wide or too long a bladder (over cuffing) may cause underestimation of blood pressure.

Source: Reference 33 (Adapted version)
9.7. Checklist for screening risk factors

In providing non-drug treatment (lifestyle modifications) advice or referrals, pharmacists could screen for the following other cardiovascular risk factors in addition to blood pressure measurements:

- Smoking
- Overweight/Obesity (BMI> 25 kg/m2)
- Low physical activity (less than 30 min of moderate physical activity 3–4 times per week)
- High total cholesterol (equal or higher than 190 mg/dl)
- Diabetes mellitus
- Men > 55 years
- Women > 65 years.

Pharmacists should be alerted for possible hypertension induced by certain medicines: oral contraceptives, oral corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDS), oral and nasal decongestants, monoamine oxidase inhibitors, ergot alkaloids, oestrogen therapy, bicarbonate, amphetamines, cyclosporine, erythropoietin, etc.


9.8. Recommended follow-up based on the management of patients with hypertension on treatment

In general, it is desirable to achieve a blood pressure level lower than 140/90 mmHg. In the case of patients with diabetes it is recommended to achieve a blood pressure lower than 130/80 mmHg.

The traditional approach to the drug treatment of hypertension has been step care.

1. If the first drug prescribed does not lead to a satisfactory fall in blood pressure, check therapeutic compliance. If this is not a problem, there may be a problem related to non-effectiveness of drug therapy and the pharmacists should, in that case, report this to the doctor or refer the patient to his/her doctor who may increase the dose or add a second drug. (In other cases, there may be a safety problem related to the medication – if the patient is having significant adverse effects, blood pressure values extremely low or no response – and the pharmacist should also report this to the doctor who may substitute an agent from other of another class). Hypertension in most patients is controlled by one or two antihypertensive agents.

2. If blood pressure is not adequately reduced with two antihypertensive agents it is worth checking that the patient is actually taking the prescribed medication. If therapeutic compliance is not the problem, refer the patient to the doctor who may increase the dose, add a third medicine or change therapy.

Pharmacists should encourage patients with hypertension on treatment to consult their GP on a regular basis and to follow the instructions and recommendations given.

Pharmacists should never forget to remind the patients about non-drug treatment of hypertension.

9.9. List of Indicators

Documentation and evaluation of the project in general

The documentation and evaluation should be performed on structure (s), process (p) and outcome (o). The data registration forms are enclosed in annex 1.

Evaluation of the programme comprises:

<table>
<thead>
<tr>
<th>Domain</th>
<th>Performance indicators:</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure</td>
<td>Collaborative programmes with other health professionals: number and characteristics (s)</td>
<td>Pharmacy files and records</td>
</tr>
<tr>
<td></td>
<td>Participation at the “training the trainers” programme: who, how and when (s)</td>
<td>Pharmacy files and records or data from the national pharmaceutical association</td>
</tr>
<tr>
<td>Quality of care</td>
<td>Patient satisfaction (o)</td>
<td>Satisfaction questionnaire (patients)</td>
</tr>
<tr>
<td></td>
<td>Professional satisfaction (o)</td>
<td>Satisfaction questionnaire (professionals)</td>
</tr>
</tbody>
</table>

The pharmacy keeps a log (Form 1) over activities connected with the project. The log is divided into three levels according to the three levels of intervention strategies. In the log they should register information on the indicators mentioned in the table.

The National Task Force receives a copy of the files and records and of the log on a pre-arranged basis (monthly or quarterly).

Ad hoc survey about professionals and patients satisfaction should be carried out. Instruments for measuring satisfaction will be provided by the Task Force Manager or obtained at national level. If translation and a national adaptation are necessary, the National Task Force will take care of this.

1. Documentation and evaluation at Level 1: Primary prevention

The documentation and evaluation should be performed on structure(s), process (p) and outcome (o). The data registration forms are enclosed in annex 1.

Evaluation at level one comprises:

<table>
<thead>
<tr>
<th>Domain</th>
<th>Performance indicators:</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect on process of hypertension prevention</td>
<td>Number of pharmacy customers to whom information about risk factors and prevention of CVD has been given (p)</td>
<td>Pharmacy log (Form 1)</td>
</tr>
<tr>
<td></td>
<td>Number of information leaflets/educational material which has been given to customers</td>
<td>Pharmacy log (Form 1)</td>
</tr>
</tbody>
</table>

The pharmacy keeps a log (Form 1) over activities connected with the project.
The National Task Force receives a copy of the files and records and of the log (monthly or quarterly).

2. Documentation and evaluation at Level 2: Detection

The documentation and evaluation should be performed on structure(s), process (p) and outcome (o). The data registration forms are enclosed in annex 1.

Evaluation at level 2 comprises:

<table>
<thead>
<tr>
<th>Domain</th>
<th>Performance indicators</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structure</strong></td>
<td>Protocols about referrals to GP (s)</td>
<td>Pharmacy files and records</td>
</tr>
<tr>
<td></td>
<td>Calibration of devices for blood pressure measurement (s)</td>
<td>Pharmacy files and records</td>
</tr>
<tr>
<td></td>
<td>Training programme and/or manual for this intervention level</td>
<td>National pharmaceutical association</td>
</tr>
<tr>
<td><strong>Effect on process of detection of hypertension</strong></td>
<td>Number of patients in which blood pressure has been measured (p)</td>
<td>Pharmacy log (Form 1) and Form 2</td>
</tr>
<tr>
<td></td>
<td>Number of patients referred to GP due to elevated BP (p)</td>
<td>Pharmacy log (Form 1) and Form 2</td>
</tr>
<tr>
<td></td>
<td>% of patients referred to the GP who returned with a prescription of antihypertensive medication</td>
<td>Pharmacy log (Form 1) and Form 2</td>
</tr>
<tr>
<td><strong>Detection of risk factors</strong></td>
<td>Number of patients in whom screenings for risk factors were performed (p)</td>
<td>Pharmacy log (Form 1) and Form 2</td>
</tr>
</tbody>
</table>

The pharmacy keeps a log over activities connected to the project as mentioned above. The registrations at level 2 should contain sufficient information for registering the indicators mentioned in the table.

The National Task Force will receive a copy of the files and records as well as a copy of the log and form 2 (monthly or quarterly).

The pharmacist keeps records of the blood pressure measurements and the performed screening for risk factors (Form 2).
3. Documentation and evaluation at Level 3: Management of hypertensive patients on treatment

The documentation and evaluation should be performed on structure(s), process(p), outcome(o) and intermediate outcome(o). The data registration forms are enclosed in annex 1.

Evaluation at level 3 comprises:

<table>
<thead>
<tr>
<th>Domain</th>
<th>Performance indicators</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure</td>
<td>Which protocol has been used for referral of patients with hypertension to GP’s (s)</td>
<td>Pharmacy files and records</td>
</tr>
<tr>
<td></td>
<td>Which protocol has been used for referral of treatment mal-functioning patients to their GP’s (s)</td>
<td>Pharmacy files and records</td>
</tr>
<tr>
<td></td>
<td>The protocols used for long-life blood pressure control (s)</td>
<td>Pharmacy files and records</td>
</tr>
<tr>
<td>Effect on process of hypertension treatment and control rates</td>
<td>Number of patients with hypertension monitored (p)</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>Number of patients with hypertension given information on drug use (p)</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>Number of drug related problems reported to the doctor</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>% of drug related problems reported to the doctor that resulted in modification of drug therapy</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>Number of patients referred to the doctor for treatment of mal-functioning patients (o)</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>Compliance with prescribed antihypertensive medicine (o)</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>Number of patients with hypertension self-monitored taught by the pharmacist (o)</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td>Effect on blood pressure management outcomes</td>
<td>Average blood pressure at the first visit (o)</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>Average blood pressure at subsequent visits (o)</td>
<td>Pharmacy log (Form 1) and Form 3</td>
</tr>
<tr>
<td></td>
<td>Satisfaction and perceived benefit (o)</td>
<td>Satisfaction questionnaire (patient) – new version</td>
</tr>
</tbody>
</table>

The pharmacy keeps a log over activities connected to the project as mentioned above. Registrations on level 3 should contain sufficient information for registering the indicators mentioned in the table.

The National Task Force will receive a copy of the files and records as well as a copy of the log and form 3 (monthly or quarterly).
The pharmacist keeps records of the blood pressure measurements and the performed screening for risk factors (Patient Profile – Form 3). Form 3 contains a table for registration of current status at repeated consultations and an overview of the current medication. The patient receives a Patient Card (Form 4) giving almost the same information as the Patient Profile – Form 3.

On a pre-arranged basis the pharmacist will send a copy of the Patient profile to the National Task Force giving information about hypertension detection, the medical treatment of the patient and control rates.
10. References


Annex 1: Forms 1–4

Form 1

Pharmacy Log

Pharmacy No ______

Report for ___________ (period)

Level one
Number of pharmacy customers at the counter to whom level one service has been given
Number of leaflets handed out in this period

Level two
Number of patients whose blood pressure has been measured in this period
Number of patients in whom screenings were performed in this period

Number of patients identified with at least one of the following CVD risk factors:

- blood pressure ≥ 140/90 mm Hg;
- men > 55 years;
- women > 65 years
- smoking;
- total cholesterol ≥ 190 mg/dL;
- diabetes;
- family history of premature cardiovascular disease.

Number of patients referred to GP due to elevated blood pressure
% of patients (referred to GP) who returned with a prescription of antihypertensive medication

Level three
Number of patients with hypertension monitored in this period
Average blood pressure at first visit
Average blood pressure at other visits
Number of patients with hypertension given information on drug use
Number of drug related problems reported to the doctor
% drug related problems (reported to the GP) that resulted in modification of drug therapy
Number of patients referred to the doctor due to mal-functioning of treatment
Number of patients capable of self monitoring blood pressure taught by the pharmacist
Pharmacist’s Patient Profile Sheet

Pharmacy code:______________________  Patient No.:____________

Sex:   M □ F □ 

Date of birth:_________________

Height: _ _ _ cm  Weight ______ kg  Blood pressure (mmHg) S/D ____/____

Risk factors (initial assessment)       Date: ________ (month/year)

Yes  No

Blood pressure ≥ 140/90 mm Hg
Man > 55 years or Woman > 65 years
Smoking
Total cholesterol ≥ 190 mg/dl
Diabetes
Family history of premature cardiovascular disease
Overweight/Obesity (BMI>25)
Low physical activity (<3h/week)
Alcohol misuse
(Male >20–30 g/day; Female >10–20 g/day)
(20g: 2 small glasses of wine or a pint of beer or 2 glasses of liquor)

Self-measurement
Teaching of BP self-measurement
Referral to GP
Visit to GP
Returned from GP with antihypertensive medication prescribed
Patients satisfaction questionnaire used

Date

Pharmacist signature and name:
<table>
<thead>
<tr>
<th>Start date</th>
<th>Stop date</th>
<th>Drug (name + dosage)</th>
<th>Frequency</th>
<th>Obs.</th>
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<td>Date</td>
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<td>Weight (Kg)</td>
<td>Pulse (bpm)</td>
<td>BP (mm Hg)</td>
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Reverse of patient card

Doctor’s name:

Phone:

Pharmacy:

Pharmacist’s name:

Phone:
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