

PHARMADIA β

**IMPROVED QUALITY IN DIABETES CARE
THE PHARMACIST IN THE ST. VINCENT
TEAM**

PROTOCOL AND GUIDELINES

JUNE 2001



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Maja Jakševac-Mikša:
President,
EuroPharm Forum

Health care of patients with diabetes is a growing economic and social problem worldwide, both because of the high incidence of the disease and the problems of employment, productivity, early disablement and mortality caused by complications, as well as the high costs of treatment.

For the above reasons, WHO, notably its Regional Office for Europe, within which the EuroPharm Forum operates, has attempted to involve all the professionals that might contribute to solving these problems or making them less severe. This was the incentive to include pharmacists, as the most easily accessible health professionals in primary health care, in diabetes care programmes along with other professionals. To help pharmacists provide extended and adequate diabetic care at the national level, EuroPharm Forum has developed the Diabetes Care project. The PharmaDiaß protocol was designed within this project in collaboration with medical practitioners (Steering Committee of St. Vincent Declaration Action Programme).

It should be noted that the EuroPharm Forum member countries have diverse health legislation, which also applies to pharmacy. As pharmacies of these countries are at different development stages, the potential for providing additional services at pharmacies is also different. It clearly follows that pharmacists of some countries will not be able to promptly adopt and implement the entire protocol and the guidelines. It is, however, certain that the protocol will help pharmacies to make some progress, small at first, towards better diabetes care, and then to design an implementation plan for subsequent phases. Here, national pharmaceutical associations should play an important role, pursuant to the guidelines.

Since implementation of the Diabetes Care project according to this protocol requires additional pharmacist training, national pharmaceutical associations of the member countries may start by including education on diabetes in the continuing education programmes for pharmacists.

Special commendation and thanks are due to Maria Augusta Soares, the author of this protocol and task force manager of the EuroPharm Forum Diabetes Care project since its very beginning. The result of her hard work and dedication is this revised and extended PharmaDiaß protocol and the guidelines helping pharmacists to get involved in the multidisciplinary team of health professionals providing diabetes care.



Mrs Maja Jakševac-Mikša, Ph. D.
President
EuroPharm Forum



Isuf Kalo:
WHO Regional Office for Europe,
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Diabetes mellitus is a chronic disease, which, due to its high and constantly increasing prevalence, its life long presence as well as its concomitant complications and disabilities, remains a major medical and social problem. It puts a heavy burden on the individuals affected, their families and society as a whole, not only financially but also in psychological and social terms.

Despite a huge network of health structures dealing with diabetes in Europe and enormous expenditure, health systems and health services have been unsuccessful in meeting what are in fact achievable objectives: curing, alleviating or substantially preventing complications.

Among several reasons for this are at least three that deserve to be highlighted:

Firstly, diabetes demands long term therapy which, in order to be effective, requires that health care providers integrate the biomedical characteristics of the disease and its treatment into a much more global or “holistic” perspective embracing four dimensions: the biomedical, the psychological, the sociological, and the educational. The effectiveness of diabetes care, as with many other chronic diseases, is strongly dependent on how well the patient masters daily management of disease.

Recognising this four-dimensional approach the World Health Organization (WHO) has fully supported and is promoting the concept of integrated therapeutic patient education as the cornerstone of effective diabetes care.

Secondly, responsibility for the management of diabetes care has rested almost exclusively with physicians and diabetes specialists without involving or creating teams and partnerships with other professionals such as nurses, pharmacists, dieticians, psychologists and educators within the framework of an interdisciplinary approach.

Thirdly, no adequate quality information systems have been established for monitoring and evaluating outcomes of health services. Thus, there is no accountability to people with diabetes, to the public or to society at large for the effectiveness of the health system in treating diabetes.

To improve the situation and the quality of diabetes care in Europe, in 1989 WHO Regional Office for Europe, in a strong collaboration with IDF Europe, initiated the St Vincent Declaration Action Programme (SVD). This has two general goals: to improve health, quality and length of life for people with diabetes and to intensify research on prevention and cure of late complications. There are several targets set for the reduction of diabetes complications, improvement of patient wellbeing and reduction of the cost and social burden related to the disease.

SVD became one of the most successful programmes in all 51 WHO Member States of Europe, 37 of which have designed a national diabetes programme for achievement of the SVD targets.

The main achievement of the SVD has been development of a new concept and introduction of new approaches to diabetes care throughout Europe:

- a unique multipartnership (people with diabetes, patient organizations, health authorities and providers, third party payers, pharmaceutical companies and the media) that shares common measurable targets;
- a common “language” for standardized data collection, enabling health care providers to communicate and compare outcomes across Europe;
- reorientation of diabetes care towards preventive and cost effective objectives, with patients in the centre, focusing on their education and empowerment;
- increasing the role of nurses, educators, family doctors, pharmacists and other specialities in the area of diabetes care through teamwork and use of a multidisciplinary approach;
- adaptation of the quality of care development concept for other chronic diseases in the Regional Office, in line with Health 21, using SVD as a model;
- a first experience in a way of thinking and acting shared throughout Europe, which was disseminated to and adapted by other WHO regions.

Among several working groups for specific targets, the group on the role of the pharmacist, of which Dr Maria Augusta Soares (Portugal) is convenor, has been extremely active and has demonstrated the strength of the partnership between the pharmacist and other health care providers in diabetes. This working group, in the framework of the EuroPharm Forum, has established a very effective network of pharmacists in diabetes care, has developed training programmes and identified quality indicators as a basis for an evaluation tool (Basic Information Sheet [BIS] for pharmacists) including patient self-monitoring, demographic and educational data and for evaluating people at risk of diabetes. This BIS will be finalized and implemented at local and national levels and aggregated data will be entered into the diabetes aggregated database hosted by the WHO Regional Office for Europe.

During the 10th anniversary meeting of the SVD in Istanbul in 1999, this working group recommended that pharmacists should:

- continue to be part of multidisciplinary teams;
- keep their knowledge of diabetes up to date;
- adapt pharmacists’ guidelines on diabetes care to local conditions.

The role of pharmacists is now extending beyond the provision of drugs to screening, diagnosis, information, education and communication with people with diabetes and to data monitoring, particularly data related to outcomes of diabetes care. To enhance this movement, a structured programme should be designed to educate pharmacists – as well as other health care providers – in provider–patient relationships, interpersonal communication, educational strategies, health beliefs, locus of control, coping with the disease, and relapse prevention as essential components of a therapeutic approach to chronic diseases.

The meeting of the EuroPharm Forum, along with the recommendations of the joint working group formed by the steering committee of the SVD Action Programme and EuroPharm Forum representatives on pharmacists’ intervention, has the potential to greatly impact the quality of diabetes care. These joint recommendations are excellent examples of cooperation not only between professionals and across sectors, but also at the international level, to improve the management of care for people with diabetes in Europe.



Preface of the first version of PharmaDiaß, 1996

The management of chronic conditions is one of the aims of EuroPharm Forum as strategies to increase pharmacist intervention to make a major contribution to healthcare.

The pharmacist increasing care on diabetes is one of strategies recommended by EuroPharm Forum to be developed together with St. Vincent Declaration Action Programme (SVD), to reduce European arising problems from diabetes, and to collaborate to set up SVD targets for diabetes.

The pharmacists in diabetes care belongs to SVD Working Group of Pharmacists, integrated in Expanding Team on Diabetes Care, so he should take his role together with other professionals for benefits of diabetes outcome in Europe.

The general Guidelines for pharmacists' intervention were published in Third Annual Meeting for St. Vincent Declaration Action Programme, held in Athens, in March/April of 1995. These Guidelines are now being detailed as essential resource for pharmacists wishing to play to enhanced role in diabetes care.

Maria Augusta Soares: EuroPharm Forum, Task Force Manager, Diabetes Care

EuroPharm Forum promotes the pharmacist in diabetes care services (PharmaDiaß) as diabetes is recognized as a growing European problem that can affect a large number of people and has severe social, economic and health consequences.

The PharmaDiaß Protocol follows the recommendations drawn up by a joint working group of the Steering Committee of the St. Vincent Declaration Action Programme (SVD) and EuroPharm Forum representatives.

The aim of the Protocol and Guidelines is to give some ideas on how the pharmacist can be involved in a multidisciplinary team, developing PharmaDiaß with other health care providers, patients and their families, patient associations and others, and promoting integrated care.

The pharmacist can collaborate with other health care providers in:

- Prevention of diabetes
- Early detection of diabetes
- Metabolic control
- Prevention of immediate and late complications of diabetes

As almost all of the European countries are implementing the St. Vincent Declaration Action Programme, the pharmacist can easily collaborate with other health care providers through PharmaDiaß and integrate his or her goals and activities with those of others at national, regional and local levels.

The Protocol and Guidelines demonstrate how pharmacists can develop their professional role of pharmaceutical care in diabetes, following Good Pharmacy Practice.

The pharmacist's main interventions are:

- To inform pharmacy customers about healthy lifestyles, to prevent or delay development of diabetes
- To target customers at risk of developing diabetes
- To make pharmacy customers aware of the need for early detection of diabetes
- To educate patients with diabetes, to help them deal with the disease
- To monitor therapeutic outcome
- To prevent, identify and solve drug-related problems
- To document and evaluate the pharmacist's intervention and patient's outcome

It is desirable that Pharmacy Associations recognize the importance of PharmaDiaß integration into each national diabetes programme based on SVD for the pharmacy profession, and that they make efforts to implement the Protocol and Guidelines.

Pharmacy Associations need to develop a planned strategy on diabetes and to provide adequate resources to achieve PharmaDiaß goals.





PHARMADIAß

PROTOCOL



1 Introduction

1.1 Background information

The WHO Regional Office for Europe and the International Diabetes Federation (IDF), Europe Region, are concerned about diabetes as it is a growing European health problem which affects all ages, in all countries, and causes prolonged illness, early death and threatens at least 10 million European citizens.

Diabetes received special attention in the 42nd WHO Assembly in 1989 when the St. Vincent Declaration (SVD) was established, together with European five-year targets to control and to prevent diabetes complications.

In Europe, diabetes prevalence is about 4–6%, but there are many people suffering from undiagnosed diabetes. The incidence of diabetes is increasing as the population is getting older and with industrialized development.

There are two forms of diabetes: type 1 and type 2. Type 2 diabetes is responsible for 90–95% of cases.

Type 1 diabetes is that in which patients need insulin for survival. Type 2 diabetes is caused by a combination of impaired insulin secretion and insulin resistance.

Type 2 diabetes prevalence (including undiagnosed cases) is 3–10% in most countries, and its prevalence and incidence increase with age.

About 10,000 children develop diabetes each year in Europe. Type 1 diabetes has a much higher incidence in Scandinavian countries and incidence appears to be rising substantially in other European countries.

Metabolic control of diabetes needs a multifactorial approach. Uncontrolled disease can lead to severe late complications of diabetes.

The main diabetes complications are:

Vascular diseases	Macrovascular	Cardiovascular disease, hypertension, atherosclerosis thrombosis, coronary heart disease, etc
	Microvascular	Retinopathy, nephropathy, etc
Neurological diseases	Autonomic neuropathy	Diarrhoea, gastroparesis diabeticorum, hypotension, etc
	Peripheral neuropathy	Neuropathic ulcers, mono- and polyneuropathy, neuropathic arthropathy, etc
Pregnancy problems	Major congenital malformation Stillbirths Prenatal mortality	
Others	Foot ulceration, gangrene, amputation, recurrent infections, skin problems	



Lifetime risk of developing diabetes is about 10–15%, with the greatest risk among children and the older population.

SVD wishes to combine efforts of all health professionals and authorities, diabetic patient associations, families and friends of people with diabetes, and others, to reduce morbidity and mortality among people with diabetes.

In Europe, pharmacists share this responsibility, as they are represented in an SVD working group – “Improving quality of diabetes care: the role of the pharmacist in the St. Vincent team” – integrated into the diabetes care team.

The SVD diabetes strategy is expanding from Europe to other World Regions, and two more movements on diabetes care, similar to SVD, were set up recently in Australia and America.

Promoting the adoption of healthy lifestyles in terms of nutrition, physical activity and ideal body weight can reduce type 2 diabetes incidence and prevalence among European citizens.

As there are concerns about the large number of the European population with undiagnosed diabetes, it is recommended that people at risk are identified and followed up for early diagnosis and treatment.

Long-term compliance with diabetes treatment is difficult, as treatment is multifactorial, combining drug treatment, nutrition care and physical activity.

It is recognized that one of the problems hindering compliance is that diabetes may exist for a long time without any severe symptoms, or even any symptoms.

As diabetes may progress in silence, it is recommended that people with diabetes should know how to deal with the disease and how to adapt all the treatment interventions to their clinical and metabolic status. To do this, they should know how to evaluate their own condition by self-surveillance¹ methodology.

As a member of the diabetes care team, the pharmacist has a useful contribution to increasing the quality of care, as:

- Pharmacists have daily contact with a large number of people
- People with diabetes have easy access to the pharmacist
- Many people look to the pharmacist for advice on health care
- Patients listen to and understand the instructions given by the pharmacist
- Pharmacists have considerable knowledge of diabetes
- Diabetes has a high incidence
- Diabetes induces severe and irreversible late complications
- There is a high rate of diabetes morbidity and mortality
- Diabetes is often diagnosed late

¹ See Chapter 12, Glossary

2 SVD recommendations for pharmacists

The joint working group of the Steering Committee of the St. Vincent Declaration Action Programme and the EuroPharm Forum representatives have drawn up recommendations for pharmacists' intervention to increase the quality of diabetes care. Pharmacists are easily accessible to members of public in all countries and they are knowledgeable about the special care needed to prevent diabetes complications and possible premature death. They are therefore a valuable resource and are willing collaborators in diabetes care at both local and national levels.

The agreed recommendations for pharmacists are:

1. Pharmacists must be responsible for keeping their basic education and skills relevant to diabetes updated, and should be encouraged to participate in postgraduate education on diabetes care.
Pharmacy technicians should be suitably trained and should work under the pharmacist's supervision.

Diabetes course curricula must include:

- Epidemiology data
 - Symptomatology and diabetes treatment interventions
 - The importance of other drug treatment (e.g. lipid lowering drugs, antihypertensive drugs)
 - Self-medication in diabetic patients
 - Immediate and late complications, and their consequences
 - Importance of early diagnosis
 - How to identify and provide advice to people at risk of diabetes
 - People at risk of developing diabetes complications and how to prevent these complications
 - The importance of rational and adequate treatment (drug and others)
 - The importance of regular self-management² and monitoring of blood glucose levels
 - How to educate people with diabetes and those at risk of developing it, in line with modern educational theory
 - How and when to refer people with diabetes to other health care providers
2. The pharmacist's activities should be integrated into local, regional and national plans and they should collaborate with the local diabetes team, diabetes associations and all other relevant partners and organizations.
 3. The pharmacist's role in primary diabetes prevention may include:
 - Promotion and counselling on healthy lifestyles
 - Participation in activities and education programmes aimed at reducing risk factors, such as obesity

² See Chapter 12, Glossary



4. Subject to national regulations and suitable facilities, the pharmacist's role in secondary diabetes prevention may include:
 - Participation in community activities (campaigns, exhibitions, special events) aimed at improving public awareness of diabetes and its symptoms, so that new cases may be diagnosed and treated without delay
 - Collaboration in national and regional screening campaigns for people at risk, in order to detect the disease early and begin prompt treatment
 - Screening people at risk of high blood glucose levels and referral to the physician when appropriate
5. The pharmacist's role in tertiary diabetes prevention may include collaboration with the diabetes care team in the support and education of people with diabetes and their families, to prevent or delay irreversible diabetes complications and to increase quality of life. The following areas should be included:
 - Drug therapy
 - Healthy nutrition
 - Physical activity
 - Foot care
 - Self-management²
 - The need for regular visits to the physician
 - The need for immediate attention by health care providers when problems develop
6. The pharmacist should have regular contact with people with diabetes and check that they have a self-management² plan, drawn up by their physicians.

Patients have to be educated about:

- Diabetes progression
 - Concordance with:
 - Drug treatment
 - Diet
 - Foot care
 - Exercise
 - Self-surveillance¹ plan
7. The pharmacist should inform patients about the medicines they dispense, and ensure that patients understand the drug:
 - Effects
 - Dosage regimen
 - Methods of administration
 8. The pharmacist's activities in diabetes care should be evaluated to demonstrate that they lead to better knowledge, concordance with treatment, overall self-management², quality of life and wellbeing (Annex 18).
 9. The pharmacist should ensure that people with diabetes are aware of the existence of Diabetes Associations and the benefits of membership.

10. Each national pharmacist organization should develop a code of practice and Guidelines for collaboration with relevant medical bodies.

Appropriate supranational bodies should develop an International Code of Practice to be followed in diabetes care.



3 Ethical Standards

Based on Good Pharmacy Practice (GPP), the Protocol and Guidelines for PharmaDiaß are carried out in accordance with the Code of Practice elaborated by the Pharmaceutical Group of the European Union (PGEU) adopted by the International Pharmaceutical Federation (FIP) and EuroPharm Forum.

The most important statements adopted by PharmaDiaß to be followed are:

- Pharmacists and other health care providers should work in cooperation, with mutual confidence in relation to all drug-related problems and the needs of people with diabetes
- Pharmacists should give the essential clinical and pharmacological information, for each person with diabetes under their care, relevant to the provision of pharmaceutical care
- Provision of pharmaceutical care is fundamental to identify and solve the patients' potential and real drug-related problems (DRPs)
- Pharmacists should inform and advise the patient, or the person taking care of the patient, on how to use their medicines in a safe and effective way to maximize therapy outcome. The language used should be adapted to the local culture and to the individual's understanding
- Education and information should respect the patient's autonomy and should empower the patient to take informed decisions about their treatment. The information should be based on good communication skills
- Provision of patient information and education should be carried out in a quiet and private area in the pharmacy
- Pharmacists are responsible for training their staff and for their attitudes towards diabetes care
- Pharmacists should be encouraged to take part in assessing patient outcome, in accordance with the Protocol and its Guidelines. It is important that the prescriber also takes part in the assessment
- Patient Medication Records (PMR) should be drawn up, with written patient's consent, and respecting the patient's privacy and confidentiality
- Pharmacists may offer to undertake biochemical and physiological tests on patients, using validated methods. This should be undertaken in cooperation with the general practitioner (GP)

4 Confidentiality and ethics of data collection

An SVD group for data collection and information systems presented a draft consensus guideline for ethical data management in diabetes information systems, which it is advisable to adopt:

- Data remains personal to the individual at all times
- Under no circumstances should personal health data be used for commercial purposes
- The process of establishing the organization of diabetes care in a district and the way clinical information and data are handled to achieve quality development within that locality is entirely a matter of consensus among professionals and people with diabetes bound by current legislation and ethics. Ethics committees have a professional duty to update their members with regard to these structures
- Optimally, a partnership, which includes the general practice community, the secondary care providers, the public health clinical domain and the patients' representatives shall jointly control any locality based system that is adopted
- Informed patient consent for identifiable information is a *sine qua non* (it remains to be seen what the ethicists will agree about the form that this should take). This should replace current practice of professional preference based on convenience. Consent must state clearly who has access to data and for what purpose. It should explicitly state that data shall only leave the local clinical domain in an anonymized form. There shall be a commitment to renew consent at stated intervals
- Those stakeholders with care and custody of any clinical data must be bound by national standards of clinical data management
- Where data are to be collected for performance monitoring both the doctor and the patient must be informed
- The design and administration of databases shall separate identifiable data for the direct care of a single patient and anonymous data to support population based care
- Since the identification of longitudinal outcomes is important in diabetes it is a matter of urgency to support the development of standard solutions for the collection, storage and analysis of identifiable and anonymized information. Such standard solutions should address the practical solution as well as the ethical guidelines
- Any methods of anonymization for longitudinal outcome purposes shall be subject to up-to-date technical and clinical assessment to verify their competence
- The system's security shall be professionally managed and written security policies should be developed and tested for current technical competence. Access audit trails will be mandatory and should be reviewed on a regular basis. Serious breaches of confidentiality should be punishable by dismissal
- Adequate and ongoing training should be available for authorized users regarding the ethical aspects of data collection and the technical aspects of data security



5 Why should pharmacists be involved in diabetes care?

5.1 Pharmacist's skills

The community pharmacist is a professional with knowledge of medicines and health care who is easily accessible to patients throughout the day. The pharmacist can therefore make a contribution to improving diabetic patients' quality of life, in collaboration with doctors and other health professionals, by informing and educating patients, answering their questions and, at the same time, monitoring the treatment they receive and their own checks on health.

The community pharmacist's involvement in diabetes care is justified by his or her position as a key member of the health care team and by the need to work together with other health professionals to prevent diabetes and its complications, as recommended by the St. Vincent Declaration Action Programme.

The reasons for this involvement can be summarized as follows:

1. The high incidence of diabetes
2. The progressive nature of the disease
3. The serious and irreversible long-term consequences of the condition
4. The decrease in quality of life induced by diabetes
5. The high rate of morbidity and mortality associated with diabetes
6. Late (in many cases, by chance) diabetes diagnosis
7. Easy access to the pharmacist
8. Pharmacists' daily contact with a large number of people
9. Many people look to the pharmacist for advice on health care
10. It is easy for the pharmacist to obtain information regularly from patients which makes it possible to speculate on the presence of disease, to assess the extent to which patients are following prescribed treatment, the quality of the patients' self checks on their condition, and the appearance or worsening of immediate or long-term complications
11. Patients listen to and understand instructions given by the pharmacist
12. Through their education, pharmacists have considerable knowledge of diabetes

To implement the Protocol and Guidelines for PharmaDiaß, pharmacists should use their skills:

- To communicate well with patients with diabetes and with the diabetes care team
- To work as a member of the team
- To act with tact, respect, empathy and diplomacy with patients with diabetes and with the diabetes care team
- To promote diabetes prevention
- To ensure that the patient is receptive to advice, information and education
- To tailor the information provided to the patient's needs and capabilities
- To consider the information needs of the carer and the family of people with diabetes, as well as those of the patient with diabetes
- To identify and overcome barriers to the pharmacist's diabetes care
- To refer patients with diabetes, as appropriate, to other health care providers

5.2 Benefits

At any time, even without appointment, patients can ask for the pharmacist's advice, as he or she is available all day.

The pharmacists can monitor the patient for knowledge, adherence and outcome of diabetes treatment and self-surveillance¹.

Through the pharmacist's involvement in diabetes care services, he or she is able to identify people at risk of developing diabetes and the patients that require more attention and care to manage diabetes in order to delay or prevent the immediate and late complications.



6 Partnership

The pharmacist should implement and develop diabetes care in collaboration with other health professionals, diabetes associations, patients and their families.

Each professional must keep their individuality but should be able to learn from and work with others, sharing information about patients.

Team work requires a clear definition of the goals and responsibilities of each professional, and their legal liabilities.

Pharmaceutical care is a patient care system based on partnership and it aims to achieve definite therapy outcome to improve a patient's quality of life.

The European pharmacist is recognized as a partner in SVD to improve the quality of care of patients with diabetes, and should work within the expanded diabetes team, providing a multidisciplinary approach to integrated care.

7 Pharmacy-based diabetes care service

In the pharmacy, patients have to receive continuous care on diabetes to increase their quality of life and wellbeing. There are various steps to be taken to implement diabetes care services in the pharmacy.

7.1 Steps for implementation

With the increasing emphasis on teamwork within primary care, a person with diabetes can benefit from the pharmacist's integration into the extended diabetes care team. It is first necessary to identify how the pharmacist can work with other health care providers and to promote ways in which they can be involved in these activities at local level, as part of the extended diabetes care team. The Pharmacy Associations should take the following steps to implement PharmaDiaß:

1. Nominate a pharmacist to manage PharmaDiaß
2. Create a national task force (NTF) comprising pharmacists and, if possible general practitioners, diabetes specialists, other health professionals and a representative of the National Diabetes Association
3. The task force should draw up a national Protocol and Guidelines, based on this document
4. If there is a national SVD task force or any other SVD group, the NTF for PharmaDiaß should liaise with their representative
5. The Pharmacy Association should ask whether a representative of their task force can join the SVD national task force or SVD national group
6. Translate and adjust this Protocol and Guidelines
7. Finalize PharmaDiaß National Protocol and Guidelines after considering comments from the representative of the SVD national task force or SVD national group
8. The PharmaDiaß task force should then discuss how to implement the agreed Protocol and Guidelines, choosing the intervention levels in pharmacy practice
9. If there is no SVD task force, the Pharmacy Association can begin alone, ideally after consulting the medical profession and the National Diabetes Association
10. The Pharmacy Association should prepare training courses in diabetes care for those pharmacists who want to develop PharmaDiaß. The courses should cover theoretical and practical aspects of diabetes care. Training should include seminars and other meetings
11. The Pharmacy Association should prepare educational material for pharmacists and pharmacy staff
12. All pharmacists should maintain up-to-date knowledge on diabetes through continuous education, promoted by the Pharmacy Association or by any other organization
13. The Pharmacy Association should be responsible for supporting and monitoring the programme implementation
14. The NTF, with experts' collaboration, should create a system of data collection



15. The NTF should periodically monitor and evaluate the outcome of the pharmacists' intervention
16. According to the EuroPharm Guidelines, the task force manager from NTF should use the European (EuroPharm Forum) data collection system to evaluate PharmaDiaß at European level.

7.2 How to get started

According to the recommendations from SVD and EuroPharm Forum, to start PharmaDiaß the pharmacists should:

- Update all aspects of diabetes care knowledge: diabetes prevention, diabetes risk factors, drug treatment, diet, foot care, self-monitoring³, physical exercise, patient information and education, communication skills, etc
- Be aware how diabetes care is organized locally, to share care and responsibilities
- Be aware that the advice, information and education given to people with diabetes should be in accordance with that given by the local diabetes team, and should agree with other proposed initiatives and goals

7.3 Pharmacist's training

To be involved in diabetes care services, the pharmacist has to maintain up-to-date knowledge and skills on diabetes and be aware of all the intervention levels and how to run each one. The pharmacist's training in diabetes and diabetes care services should be done continuously and it should cover both theory and practice. The domains of the recommended training are as follows.

7.3.1 Theoretical training on diabetes

Part A

- Epidemiology of diabetes
- Classification of diabetes mellitus and other categories of glucose intolerance
- Aetiology of diabetes
- Diagnosis
- Insulin secretion and metabolic effects
- Clinical, metabolic and biochemical effects of diabetes
- Diabetes in special conditions: children, pregnancy, elderly, etc
- Immediate diabetes complications: prevention, identification and treatment:
 - Hypoglycaemia
 - Diabetic ketoacidosis and hyperglycaemic non-ketotic coma
 - Infections, immunity and diabetes

³ See Chapter 12, Glossary

- The main late diabetes complications:

Vascular diseases	Macrovascular	Cardiovascular disease, hypertension, atherosclerosis thrombosis, coronary heart disease, etc
	Microvascular	Retinopathy, nephropathy, etc
Neurological diseases	Autonomic neuropathy	Diarrhoea, gastroparesis diabeticorum, hypotension, etc
	Peripheral neuropathy	Neuropathic ulcers, mono- and polyneuropathy, neuropathic arthropathy, etc
Pregnancy problems	Major congenital malformation Stillbirths Prenatal mortality	
Others	Foot ulceration, gangrene, amputation, recurrent infections, skin problems	

- Diabetes therapeutic goals
- Non pharmacological therapy:
 - Nutrition care
 - Physical activity
 - Hygiene
 - Others
- Pharmacological treatment: selection criteria, drug pharmacology, patient information and patient follow up:
 - Insulin
 - Oral antidiabetic drugs
 - Other drugs used in diabetic patients
- Minor diseases treatment in diabetic patients
- Diabetic patients' monitoring:
 - Clinical;
 - Laboratory.
- Self-monitoring³:
 - Symptoms;
 - Blood/urine glucose
 - Weight control
 - Foot surveillance
 - Hygiene
- Travelling with diabetes
- Patient information and education
- Pharmacist and diabetes: intervention for quality of care

Part B

- St. Vincent Declaration action programme
- PharmaDiaß programme
- Levels of pharmacist intervention
- Documentation system



- Evaluation of pharmacist's activities at:
 - Patient level
 - Pharmacy level
 - National level
 - International level

Part C

- Communication skills
- Patient education

7.3.2 Practical training on diabetes

- Communication skills (with patients and doctors)
- How to use devices for self-monitoring of blood or urine glucose
- How to manage different insulin “pen” devices
- Clinical case studies

7.3.3 Seminars on diabetes

To maintain up-to-date knowledge and skills about diabetes, pharmacists should regularly attend seminars and other courses (2–3 times each year). These seminars will allow pharmacists to share their knowledge with colleagues.

7.3.4 International meetings on diabetes

It is advisable, if possible, to attend some international meetings (held annually), as for example:

- EASD – European Association for Study on Diabetes
- ADA – American Diabetes Association

7.4 Purpose of the Protocol and Guidelines

The purpose of the Protocol and Guidelines is to provide community pharmacists with tools for dealing with diabetes in everyday practice. This means primary, secondary and tertiary diabetes prevention.

The Protocol and Guidelines focus on providing a systematic and structured approach to pharmacy-based diabetes care services, including documentation of the pharmacist intervention and the outcome.

The Protocol provides European Pharmacy Associations with a tool for implementing diabetes care services within the framework of Good Pharmacy Practice (GPP).

7.5 Objectives

The main objectives of the Protocol are to:

- Promote diabetes prevention
- Increase early diagnosis of diabetes
- Improve knowledge and skills of patients with diabetes in dealing with their treatment, to reduce the severity and incidence of immediate and late diabetes complications
- Improve the wellbeing of patients with diabetes

At European level, the objectives of the Protocol, are to:

- Promote PharmaDiaß implementation in as many countries as possible
- Aggregate the data from the involved countries to provide an overview of the European situation

At national level, the objectives of the Protocol, are to:

- Promote PharmaDiaß implementation, together with the national structures for St. Vincent Declaration Action Programme, based on Guidelines

At pharmacy level, the objectives of the Protocol are to:

- Raise awareness of pharmacists and pharmacy staff of the importance of focusing their intervention on diabetes care
- Promote the diabetes care services, together with other health care providers and diabetes associations
- Implement the pharmacist services at three action levels, recommended by the SVD: primary, secondary and tertiary diabetes prevention
- Improve the clinical and psychosocial outcome of patients with diabetes
- Document the pharmacists' intervention on diabetes care services
- Document output and outcome of the diabetes care services

At population and patient levels, the objectives of the Protocol are to:

- Raise awareness among the population about diabetes and its importance to public health
- Provide information to the public on how lifestyle changes can delay or prevent diabetes onset
- Promote the early identification of patients with diabetes
- Increase patient compliance and concordance to treatment
- Increase patients' metabolic control;
- Increase quality of life of patients with diabetes
- Increase wellbeing of patients with diabetes



8 Intervention model

The PharmaDiaß Protocol deals with several aspects of diabetes care within five main elements of GPP defined in the WHO document, focusing on type 2 diabetes.

1. Health promotion and ill-health prevention
2. Supply and use of prescribed and OTC medicines, and other diabetes health care products
3. Self-care
4. Identification of drug-related problems and their solution
5. Influencing prescribing and medicines use

The Protocol mainly focuses on the pharmacist's services for early identification of people with diabetes, diabetes self-care, self-monitoring³ and the supply and use of prescribed medicines and other health products. It recognizes the importance of identifying and resolving drug-related problems, with referral to the doctor if necessary. It provides checklists of pharmacist's activities within these areas.

8.1 Level 1:

To promote the adoption of healthy lifestyles to prevent diabetes

There are some modifiable risk factors, such as obesity and sedentary lifestyle, which are recognized as being strongly linked to the incidence of type 2 diabetes.

Healthy lifestyles should be promoted to all people, but particularly to those at risk of developing type 2 diabetes (because of known unmodifiable and modifiable risk factors).

This action level can be provided by all trained pharmacy staff, in all pharmacies, as a systematic approach to people at risk.

The objectives of this level are to promote:

- Physical activity
- Ideal body mass index (BMI)
- Healthy nutrition
- Smoking cessation and prevention
- Reduction in salt intake
- Reduction in alcohol intake

Target population:

The first action level for diabetes prevention is targeted to people who have known risk factors for diabetes for whom the adoption of a healthy lifestyle can delay or prevent diabetes onset.

8.2 Level 2: To collaborate in early diabetes detection

Many patients with diabetes are diagnosed some years after the disease has begun, at which point they are already suffering from diabetes complications. Early diagnosis is therefore of great importance.

This intervention level should be provided by all pharmacists trained in identification of diabetes signs or symptoms and/or in screening blood glucose (if allowed).

The objectives of this level are to:

- Alert people at risk of type 2 diabetes to be aware of disease onset by signs or symptoms or by periodic checking of their blood glucose levels
- Refer to the physician people presenting with diabetes signs or symptoms
- Refer to the physician people with high blood glucose levels
- Request the referred people to return to the pharmacy, if possible, to provide information about the diagnosis

Target population:

The second action level concerns the pharmacist's collaboration in early diabetes diagnosis. The target population for this is the pharmacy customer who presents with signs/symptoms of diabetes and/or who has hyperglycaemia in the pharmacy test (if allowed).

People at risk for type 2 diabetes include those:

- Over 40 years old
- With type 2 diabetes in the family
- Obese
- Women with child(ren) over 4 kg at birth
- Women with gestational diabetes

Signs or symptoms that should raise suspicion of type 2 diabetes include:

- Frequent thirst
- Dry mouth
- Sudden hunger episodes
- Passing large amount of urine
- Tiredness
- Weight loss
- Genital itching
- Repeated urinary infections
- Blurred vision



8.2.1 Practices

a. Essential practice

Identify people with suspected undiagnosed diabetes by monitoring OTC sales and customer's complaints when responding to the symptoms mentioned above, and when customers complain of cystitis, vaginal thrush, or persistent skin infections.

b. Desirable practice

Offer to screen blood glucose in the pharmacy (if it is allowed), and collaborate in screening campaigns run by other health care providers.

8.3 Level 3:

Outcome oriented patient counselling and monitoring

At the third action level, the pharmacist can provide support, information and education and can monitor people with diabetes. Education alone does not necessarily lead to improvement. It is important to provide information in a way that motivates the patient to change behaviour.

The third level of PharmaDiaß intervention is to be developed just by the trained pharmacists in their pharmacies.

The objectives of this level are to ensure pharmaceutical care provision by:

- Assessing the prescription for any drug interaction, contraindication or any other problem
- Checking the dosage regimen for antidiabetic drugs
- Systematic identification and assessment of any drug-related problem (DRP)
- Choosing and implementing the best solution for the DRP in cooperation with the patient and his or her doctor
- Ensuring that the patient understands the use and effects of the medication
- For patients on insulin, checking their knowledge about storage requirements, stock control, injection technique, and disposal of used needles and syringes
- Ensuring patient knowledge and concordance with other aspects of diabetes care, e.g. nutrition; physical activity; blood glucose self-monitoring³; foot care; hypoglycaemia prevention, identification and treatment; the use of a diabetes passport; physician surveillance; smoking cessation; alcohol intake; salt intake; weight reduction and control
- Advocating membership of a Diabetes Association
- Checking on progress
- Empowering patients with type 2 diabetes to manage their condition to prevent diabetes complications and to experience a good quality of life and wellbeing

Target population:

The third action level has, as target population, those pharmacy customers, mainly type 2 diabetics, who will benefit from pharmaceutical care services and who agree to be included in the programme.

Patients that benefit most from the pharmacist's intervention are those who present with other risk factors for late diabetes complications, e.g. hypertension, elevated blood lipids, microalbuminuria, wounds.



9 How to use the Protocol

The Protocol is to be used at several action levels:

9.1 European level

9.2 National level

The Protocol is to be used as a tool for PharmaDiaβ services implementation at country level, as a:

- Basis for PharmaDiaβ national, regional and/or local activities
- Basis for a research project to study the feasibility of diabetes care services and documentation

9.3 Pharmacy level

The Protocol can be used at the pharmacy for implementation of PharmaDiaβ services, according to the skills and ability of the pharmacist and patient needs.

9.4 Population and patient levels

9.5 Steps for PharmaDiaβ

The introduction of the pharmacist's intervention can follow the Steps for implementation (7.1)

10 Pharmacy Association responsibilities

To improve the quality of care on diabetes, pharmacists should play a role oriented by the Pharmacy Association strategy. In this respect, the responsibilities of the Pharmacy Association are to:

- Define the intervention levels
- Establish the national, regional and local intervention strategy
- Nominate a pharmacist as task force member to EuroPharm Forum, for pharmacy-based diabetes services
- Promote the establishment of a national task force for PharmaDiaß
- Aim to have at least one pharmacist in the national group for SVD
- Promote training courses
- Prepare or adopt scientific documentation for pharmacists
- Prepare written information for customers and patients
- Create a documentation system and promote data collection and evaluation
- Use data to document the pharmacist's intervention and quality of care improvement



11 References

1. STEVEN, A.S.; KRUPP, M.A.; TIERNY, L.M.: Current Medical Diagnosis and Treatment; Norwalk, Appeton and Lange, 1988, p. 749
2. KATAZUNG, B.G.: Basic and Clinical Pharmacology, 3rd ed.: Norwalk, Appeton and Lange, 1987, p. 484
3. GARRET, J.; OSWALD, W.: Terapêutica Medicamentosa e suas Bases Farmacológicas – Manual de Farmacologia e Terapêutica, 2nd ed.: Porto, Porto Editora, 1987, p. 859
4. RAKEL: Conn's Current Therapy: Philadelphia, W.B. Sanders Company, 1988, p. 462–473
5. SPEIGT, M.: Avery's Drug Treatment – Principles and Practice of Clinical Pharmacology and Therapeutics, 3rd ed.: Aucklan, Adis Press, 1987, p. 522
6. HERFINDAL; HAIRSCHMAN, J.L.: Clinical Pharmacy and Therapeutics, 3rd ed.: Baltimore, Williams & Wilkins, 1984, p. 546
7. HANSTEN; HORN, J.R.: Drug Interactions, Clinical Significance of Drug – Drug Interactions, 6th ed.: Philadelphia, Lea & Febier, 1989
8. GRIFFIN; D'ARCY, P.F.: A Manual of Adverse Drug Reactions, 3rd ed.: Bristol, Weight, 1984
9. GOODMAN AND GILMANS: The Pharmacological Basis of the Therapeutics, 7th ed.: New York, MacMillan Publishing Company, 1985, p. 1490–1512
10. KNOBEN, J.E.; ANDERSON, P.O.: Handbook of Clinical Drug Data, 6th ed.: Hamilton, Drug Intelligence Publications, 1988
11. Associação Protectora dos Diabéticos de Portugal: Diabetes e Saúde Pública, Lisbon, Publicações Ciência e Vida Lda., 1987
12. LISBOA, P.E. et al: Tópicos sobre Diabetes: Lisbon, 1991
13. PIGNATELLI, D.; CARVALHO, D.: ABC da Diabetes: Lisbon, Europress Editores e Distribuidores de Publicações, Lda
14. REICHART, P.: A Risk–Benefit Assessment of Conventional Versus Intensive Insulin Therapy: Drug Safety, 1994, 10 (3), p. 196–201
15. European Union Pharmaceutical Group: Livro Branco da Farmácia Europeia: published by the Ordem dos Farmacêuticos and the Associação Nacional de Farmácias
16. Good Pharmacy Practice in Europe (G.P.P.) – approved by the 3rd Annual Convention of the EuroPharm Forum: WHO 1994

17. The Role of the Pharmacist: Quality Pharmaceutical Services – Benefits for Governments and for the Public: 2nd WHO Convention, Tokyo, Aug/Sept 1993
18. Diabcare, The St. Vincent Declaration, Newsletter Issue 3, Spring 1993, p. 7
19. Diabcare, Minutes: Ninth Steering Committee Meeting of the St. Vincent Declaration Action Programme for Diabetes Care and Research in Europe: WHO European Regional Office, Copenhagen, 8–9 Jan 1993
20. Direcção Geral dos Cuidados de Saúde Primários: Orientações Técnicas 7, Lisbon, 1992
21. BOOTH, C.D.; WALKER, R.: Pharmaceutical Care: Counselling Patients with Diabetes: European Society of Clinical Pharmacy (Proceeding of the 22nd European Symposium of Clinical Pharmacy), Oct 1993, p. 152–154
22. PAOLISSO, G. et al: Insulin Resistance and Hypertension in Elderly, *Drug and Aging*, 4 (5), 1994, p. 404–409
23. Papers to Change Practice: Risk of Long-Term Complications of Diabetes Mellitus Reduced by Tight Blood Sugar Control: *Drug and Therapeutic Bulletin*, 32 (5), 1994, p. 40
24. HIGGINS, G.: Applying the New DCCT Results to New Patient Group – Is It Feasible?: *Inpharma (Views and Reviews)*, 1994
25. CHAN, T.Y.K. et al: Recurrent Glibeclamide-Induced Hypoglycemia: The Importance of Obtaining a Comprehensive Medication: *The Annals of Pharmacology*, 28 Jan 1994, p. 199
26. Defining the Next Steps for Self-Medication in Europe: *OTC Bulletin*, June 1994, p. 10–11
27. VAZ, A.F.: O Clínico Geral e o Farmacêutico: *Informação Terapêutica*, Ano II, Nº 2, 1993, p. 7
28. Insulin Pumps. *Lancet*, 1994, p. 343, 514–515
29. Prevention of Diabetes Mellitus: WHO Technical Report Series 844 (Report of a WHO Study Group), Geneva, 1994
30. Annual Report of the Executive Committee of the EuroPharm Forum, Copenhagen, 24 May 1994, p. 3
31. Draft Guidelines on the Role of the Pharmacist in Diabetes Care, Copenhagen, March 1994
32. The Role of the Pharmacist in the Health Care System (Report of a WHO Consultative Group): WHO, Geneva, 1990
33. FIP Standard for Quality of Pharmacy Services, The Tokyo Declaration, Aug/Sept 1993



34. Role of the Pharmacist in the Health Care System: WHO, Geneva, 1990
35. Prevention of Diabetes Mellitus; Report of a WHO Study Group; WHO Technical Report Series no. 844, Geneva; 1994
36. Guidelines for the development of a National Programme for Diabetes Mellitus; WHO Division of Non-communicable Diseases and Health Technology; Geneva 1991.

12 Glossary

¹ **Self-surveillance** means that the patient regularly checks:

- diabetes symptoms
- diabetes complications, signs or symptoms
- blood glucose levels
- urine glucose levels
- body weight
- feet
- infection signs

It is to be done under physician prescription and pharmacist monitoring.

² **Self-management** means that the patient has to learn how to deal with the disease and its treatment to get metabolic control.

It is to be done under physician prescription and pharmacist monitoring.

³ **Self-monitoring** means patient monitoring of capillary blood glucose and/or urine glucose.

It is to be done under physician prescription and pharmacist monitoring.



PHARMADIA β

GUIDELINES



1 Guideline 1: Guideline for promoting healthy lifestyles

The objectives of the PharmaDiaß services at this level of action should be promoted to all customers, but especially to those with known risk factors for type 2 diabetes.

The intervention can be carried out by all trained pharmacy staff.

1.1 Background information

Certain risk factors for type 2 diabetes can be identified and modified to prevent or delay diabetes onset.

Some authors strongly believe that the rising world prevalence of type 2 diabetes is related to unhealthy lifestyle.

The main risk factors that can be identified and modified by the adoption of a healthy lifestyle are:

- High body mass index (BMI);
- Sedentary lifestyle (physical inactivity)
- Unhealthy nutrition
- Smoking
- Excess alcohol intake

People with highest risk for diabetes, who deserve particular attention, are those with both modifiable and unmodifiable risk factors. Unmodifiable risk factors for type 2 diabetes include:

- Family history of type 2 diabetes
- Women with children heavier than 4 kg at birth
- Women with gestational diabetes

The pharmacist is in an ideal situation to recommend the care that individual customers need for diabetes prevention:

- Healthy nutrition by:
 - Increasing the number of daily meals (eating small portions more often)
 - Reducing fat, salt and alcohol intake
 - Increasing fibre, water and milk intake
 - Reducing daily calorie intake
- Reducing BMI to achieve and maintain an ideal level by:
 - Healthy nutrition
 - Promotion of physical activity



Pharmacists, knowing their customers' risk factors, can promote the adoption of healthy lifestyles, to ensure:

- Customers' awareness about their diabetes risk factors
- That customers are given information on how they can prevent or delay diabetes onset through the adoption of healthy lifestyles
- Follow up of customers to check their compliance and concordance with diabetes prevention behaviour

1.2 Objectives

The objectives of this procedure are to ensure that pharmacy customers with known unmodifiable and modifiable diabetes risk factors receive information and advice on:

- Their modifiable risk factors
- How they can change their behaviour to prevent or delay type 2 diabetes onset

1.3 Scope

The services within this procedure are targeted to pharmacy customers with known modifiable type 2 diabetes risk factors.

The procedures cover the following areas of pharmacy services:

- a. Informing customers about their risk factors for type 2 diabetes (modifiable and unmodifiable)
- b. Informing customers about type 2 diabetes and its complications
- c. Informing customers about the benefits of adopting healthy lifestyles and changing their behaviour to reduce type 2 diabetes risk factors
- d. Informing customers how to change nutrition to lose weight if needed and recommending physical activity
- e. Informing customers about risk factors for diabetes complications to be avoided or reduced: smoking, excess salt and alcohol intake
- f. Providing information leaflets about the most important subjects: smoking, alcohol intake, weight control, diabetes, healthy nutrition, physical activities, etc
- g. Advising customers at risk, especially those above 40 years old, on periodic screening of their blood glucose level

1.4 Process

The information and advice given by the pharmacy staff comprises the following:

- Customers' evaluation for unmodifiable type 2 diabetes risk factors and confirmation of whether they have modifiable type 2 diabetes risk factors
- Customers' information about type 2 diabetes and its complications, and risk factors that should be changed
- Customers' evaluation for any other health risk factor, e.g. smoking, excess alcohol and salt intake, and how to reduce these
- Customers' information on how to change type 2 risk factors by adopting healthy nutrition, losing weight and taking regular physical exercise

- Customers' evaluation for written information needs and provision of information leaflets on diabetes and related subjects
- Customers' commitment to make their relatives aware about diabetes risk factors.

1.5 Responsibilities

1.5.1 Pharmacy Association responsibilities

In each country, the Pharmacy Association is responsible for:

- Preparation of written information for customers
- Promotion of:
 - Pharmacists' training courses (theoretical and practical)
 - Provision of weight measuring devices in the pharmacy
 - Educational material
 - Data collection system: forms and data base
 - Intervention and outcome documentation

1.5.2 Pharmacist's responsibilities

- Organising and structuring the pharmacy service
- Training the pharmacy staff to identify the customer's risk factors for type 2 diabetes
- Training the pharmacy staff to give information about healthy lifestyles, tailored to customer needs
- Assessing the customer for presence of modifiable and unmodifiable type 2 diabetes risk factors
- Informing the customer on how to adopt a healthy lifestyle to reduce type 2 diabetes risk factors
- Using communication skills to question and inform customer
- Handing out written information leaflets, according to customer needs
- Using Protocols for counselling, when advising patients

1.6 Structure and requirements

1.6.1 Training

The pharmacy staff should receive appropriate training about:

- Type 2 diabetes and its complications
- Modifiable and unmodifiable type 2 diabetes risk factors
- Communication skills
- Questioning and information techniques
- Healthy lifestyles for type 2 diabetes prevention
- Documenting the intervention and outcome

1.6.2 Quiet area

The pharmacist should organize the pharmacy to have a quiet area for customer consultation.



1.6.3 Basic knowledge in communication process

The communication process is related to the customer and the physician.

1.6.3.1 Communication with customer

Among other fundamental issues, when communicating with customers the pharmacy staff should:

- Face the customer
- Use a questioning technique to ensure that the customer gives relevant information
- Coordinate the dialogue

1.6.3.2 Communication with physician

Communication with the physician should be done carefully for the benefit of the patient.

1.6.4 Tools

- To be handed out to the customers at risk:
 - Written information material about healthy lifestyles
 - Written material about type 2 diabetes
 - Written information about modifiable and unmodifiable diabetes risk factors
- To have in the pharmacy:
 - Weight measuring device
 - BMI table
 - Model letter to refer customer to the physician
 - Forms to document the intervention and outcome

1.7 Documentation

The pharmacy staff intervention has to be recorded using indicators to evaluate the intervention. The structure, process and outcome indicators at customer, pharmacy, national and international levels should be considered.

1.7.1 Indicators at customer's level

1.7.1.1 Structure

- Customer's receptivity

1.7.1.2 Process

- Responding to the structured questionnaire.

1.7.1.3 Outcome

- Customer's satisfaction
- Healthy lifestyle followed

1.7.2 Indicators at pharmacy level

1.7.2.1 Structure

Available in the pharmacy:

- Standard structured questionnaire
- Weight measuring device
- BMI table
- Customer leaflets
- Record forms
- Trained pharmacy staff

Example of a structured questionnaire:

- Customer aged over 40 years old?
- Type 2 diabetes in the family?
- Overweight customer (BMI > 25)?
- Waist/hip ratio > 1?
- Female with child(ren) > 4 kg, at birth?
- Female with gestational diabetes in at least one pregnancy?
- Sedentary lifestyle?
- Passing large amount of urine?
- Repeated infections (urinary, vaginal)?
- Any chronic disease? Which one?
- Medication taken? Which drugs?

Example of themes for pharmacy staff training:

- Diabetes epidemiology
- Diabetes definition and classification
- Diagnosis criteria
- Type 2 diabetes modifiable and unmodifiable risk factors
- Healthy lifestyles to prevent or delay diabetes onset
- Communication skills

Examples of themes for customer's leaflets on diabetes:

- What is diabetes and what are its complications?
- What are the unmodifiable diabetes risk factors?
- What are the modifiable diabetes risk factors?
- How to change diabetes risk factors and the benefits of doing this

1.7.2.2 Process

- Structured questionnaire used
- Weight measurement done
- BMI calculated
- Diabetes leaflet handed out
- Intervention recorded



1.7.2.3 Outcome

- Pharmacy customer identified as having diabetes risk factor(s)
- Type of identified risk factor
- Type of verbal advice given
- Customer's adoption of lifestyle to change his or her risk factors

1.7.3 Indicators at national level

1.7.3.1 Structure

- Pharmacies involved in primary diabetes prevention
- Pharmacy staff trained

1.7.3.2 Process

- Leaflets handed out to customers with known diabetes risk factors

1.7.3.3 Outcome

- Type of modifiable diabetes risk factor identified
- Type of advice/information given to the customers
- Customers who adopted lifestyles to change diabetes risk factors

1.7.4 Indicators at international level

1.7.4.1 Structure

- Countries with customer's leaflet on diabetes
- Countries with training courses for pharmacy staff

1.7.4.2 Process

- EuroPharm Forum countries involved in primary diabetes prevention.

1.7.4.3 Outcome

- EuroPharm Forum countries involved in primary diabetes prevention that have identified customers with modifiable risk factors:
 - Obesity
 - Physical inactivity
 - Unhealthy nutrition

1.8 Checklists to identify people at risk of diabetes

1.8.1 Materials

- Record forms to evaluate pharmacy and national pharmacists' intervention
- Model letter to refer customers to the physician
- Information leaflets to be handed out, about:
 - Type 2 diabetes
 - Type 2 diabetes risk factors (modifiable and unmodifiable)
 - Healthy lifestyles for prevention or delay of type 2 diabetes
 - How to adopt healthy lifestyles
 - When to seek a medical consultation

1.8.2 Questioning technique

The use of a structured questioning technique ensures that objective and subjective data are collected to evaluate customers' risks of type 2 diabetes and to identify customers with modifiable risk factors. A solution (promotion of healthy lifestyle or/and referral) can then be recommended.

- Who is the customer?
- History of diabetes/early cardiovascular disease in patient's family?
- Does the customer have unmodifiable type 2 diabetes risk factors? Which are they?
- Which are the customer's modifiable type 2 diabetes risk factors?
- Is the customer taking any medication, which could induce type 2 diabetes risk factors or diabetes signs/symptoms?
- Is the customer wishing to adopt a healthier lifestyle to prevent or delay onset of type 2 diabetes?

The use of open-ended questions encourages the customer to talk, which helps the pharmacy staff to understand the customer's condition.

Information should be delivered according to the individual customer's needs and type 2 diabetes risk factors.

1.8.3 Regular customer's assessment and information

Every time the customer comes to the pharmacy, he or she should be evaluated for compliance with the advice given on healthy lifestyle.

The customer should be kept informed about diabetes care and any questions clarified.

1.8.4 Referral

Customers who have difficulty in following the pharmacist's advice, or those who have severe type 2 diabetes risk factors, should be referred, with a letter, to the physician.



2 Guideline 2: Guideline for detecting undiagnosed diabetes

Community pharmacists are in an ideal situation to identify undiagnosed people with suspected type 2 diabetes.

The intervention should be carried out by trained pharmacists, in the pharmacies integrated in PharmaDiaß.

The pharmacy staff should be instructed to collaborate, referring people in whom diabetes is suspected to the pharmacist (or to trained pharmacy staff) for evaluation.

Guideline 2 should be used for those people who complain of signs or symptoms that could indicate diabetes. It also includes those people who have high blood glucose level (in a pharmacy test, if allowed).

2.1 Background information

Type 2 diabetes is often diagnosed several years after its onset, because diabetes is a silent syndrome in which symptoms and signs are usually absent or people are not able to recognize them. By the time the disease is diagnosed, microvascular complications are present in up to 50 per cent of patients.

It is important to identify people suffering from type 2 diabetes as soon as possible after the onset to begin proper treatment and so to delay or to prevent late diabetes complications.

Type 2 diabetes symptoms include:

- Frequent thirst
- Dry mouth
- Sudden hunger episodes
- Passing large amount of urine
- Tiredness
- Weight loss
- Genital itching
- Repeated urinary infections
- Blurred vision

Type 2 diabetes signs include:

- Obesity
- Weight loss
- Age over 40 years old
- Family history of type 2 diabetes
- Women with gestational diabetes or those who have had a child heavier than 4 kg are also at risk for type 2 diabetes.

Pharmacist can identify diabetes symptoms and signs in their customers and refer them to the physician for clinical and laboratory assessment.

The trained pharmacists can also assess blood glucose level (if allowed) or offer support to local screening campaigns run by other health care professionals.

Pharmacists should follow up the results of doctor assessment to find out if a diagnosis of diabetes is made.

2.2 Objectives

The objectives of this procedure are to ensure that pharmacy customers suffering from unknown diabetes are diagnosed as soon as possible, through the pharmacists' collaboration, referring the suspected people to their doctors for evaluation and diagnosis.

People with type 2 diabetes are identified by signs/symptoms or by hyperglycaemia. Early diagnosis and treatment can reduce the risk of late complications of diabetes.

2.3 Scope

The services within this procedure are targeted to pharmacy customers, with:

- Known type 2 diabetes signs/symptoms
- Hyperglycaemia

The procedures cover the following areas of pharmacy services:

- a. Assessing signs/symptoms of type 2 diabetes
- b. Detecting hyperglycaemia (if allowed in the pharmacy)
- c. Informing customers about type 2 diabetes and its complications
- d. Informing customers about the benefits of early diagnosis
- e. Referring suspected people to the physician
- f. Handing out an information leaflet about diabetes
- g. Giving the customer a letter to take to the physician about their condition
- h. Gaining commitment of the customer to return to the pharmacy to give information about the physician's assessment (diagnosis)

Note that occasional hyperglycaemia does not mean that a person is suffering from diabetes, but they should be referred to the doctor for evaluation.

2.4 Process

The process comprises the following services:

- The pharmacist evaluates customers' signs/symptoms, according to those of type 2 diabetes
- Evaluation of customers' medication for side effects that might look like type 2 diabetes or induce hyperglycaemia



- If the customers' signs/symptoms raise the suspicion of diabetes, pharmacists can perform a blood glucose test (if allowed) and compare data with WHO (SVD) reference values for diabetes
- If the customer is suspected of suffering from diabetes (by signs/symptoms or hyperglycaemia), he or she should be referred to the physician
- When the patient is referred, he or she should receive an explanatory letter from the pharmacist to take to the physician
- The customer should be asked to come back to the pharmacy to give information about the outcome of the doctor's consultation and the diagnosis
- The customer with suspected type 2 diabetes should be given a diabetes leaflet, handed out by the pharmacist.

2.5 Responsibilities

2.5.1 Pharmacy Association responsibilities

In each country the Pharmacy Association is responsible for the level 2 PharmaDiaß promotion in pharmacies, for pharmacist training, preparation of written material, etc.

The Pharmacy Association is responsible for:

- Preparation of written information (leaflets) for customers about diabetes, diabetes complications and the benefits of early diagnosis
- Promotion of the provision of weight measuring devices in pharmacies
- Promotion of pharmacists' training courses about diabetes signs/symptoms and blood glucose measurement technique and interpretation (if allowed)
- Promotion of a system of data collection: forms and database

2.5.2 Pharmacist's responsibilities

The pharmacist is responsible for identifying customers with suspected type 2 diabetes, referring them to the physician with a referral letter and gaining their commitment to return to the pharmacy after the consultation.

In each pharmacy, the pharmacist is responsible for:

- Organising and structuring the pharmacy services
- Training the pharmacy staff to refer people with suspected type 2 diabetes to the pharmacist
- Keeping their knowledge about diabetes updated
- Identifying suspected type 2 diabetes by signs and symptoms
- Performing blood glucose tests (if allowed)
- Referring people with suspected type 2 diabetes
- Gaining the commitment of customers to come back to the pharmacy, after physician consultation
- Following up the customers, in accordance with the outcome

2.5.3 Pharmacy staff's responsibilities

- Refer people with signs/symptoms of type 2 diabetes to the pharmacist.

2.6 Structure and requirements

2.6.1 Training

The pharmacist should undergo appropriate training about:

- Diabetes and its complications
- Diabetes signs/symptoms
- Questioning and information techniques
- Communication skills
- Documenting intervention and outcome

2.6.2 Quiet area

Each pharmacy integrated in PharmaDia β should organize the pharmacy so that there is a quiet, private area for customer or patient consultation.

2.6.3 Pharmacist's knowledge

Pharmacists should be trained on how to perform blood glucose tests and on evaluation of data according to the test conditions and diagnosis values proposed by WHO, in countries where pharmacists are allowed to perform these tests in the pharmacy.

2.6.4 Basic knowledge in communication process

See basic rules in Guideline 1.

2.6.5 Resources

- Patient's written information material about type 2 diabetes signs/symptoms and diabetes risk factors
- Patient's written information material about blood glucose values and their interpretation
- Patient's leaflets about diabetes
- Weight measuring device
- BMI table
- Blood glucose monitoring devices and related material (if allowed)
- Model letter to refer the customer to the physician
- Forms to document the intervention and the outcome

2.7 Documentation

The pharmacist's intervention should be recorded, using relevant indicators.



The structure, process and outcome indicators at customer, pharmacy, national and international levels should be considered.

2.7.1 Indicators at customer's level

2.7.1.1 Structure

- Customer's receptivity.

2.7.1.2 Process

- Responding to the structured questionnaire.

2.7.1.3 Outcome

- Customer's satisfaction
- Customer's agreement to physician appointment
- Customer's commitment to return to the pharmacy after seeing the doctor

2.7.2 Indicators at pharmacy level

2.7.2.1 Structure

Existence in the pharmacy:

- Standard structured questionnaire
- Trained pharmacists
- Weight measuring device
- BMI table
- Customer leaflets
- Recording forms
- Model letter to the doctor
- Basic Information Sheet for Pharmacist (BISP)

Example of a structured questionnaire:

- What do you feel exactly?
- Do you have sudden episodes of hunger?
- Do you sometimes feel faint?
- Have you gained weight?
- Have you lost weight?
- Do you pass a large amount of urine?
- Do you have repeated urinary and vaginal infection?

Example of themes for pharmacy staff training:

- Diabetes epidemiology
- Diabetes definition and classification
- Diagnosis criteria
- Type 2 diabetes modifiable and unmodifiable risk factors

- Diabetes signs/symptoms
- Healthy lifestyles to prevent or delay diabetes onset
- Communication skills

Examples of themes for customer's leaflets on diabetes:

- What is diabetes and what are its complications?
- What are the diabetes risk factors?
- What are the modifiable diabetes risk factors?
- How to change diabetes risk factors and the benefits of doing this
- Diabetes signs/symptoms
- Diagnosis criteria

2.7.2.2 Process

- Structured questionnaire used
- Weight measurement taken
- BMI calculated
- Diabetes leaflet handed out
- Intervention recorded
- Model letter sent to the doctor
- BISP completed and sent out

2.7.2.3 Outcome

- Pharmacy customer identified as having diabetes signs/symptoms
- Customer's agreement to see the doctor
- Customer diagnosed by the doctor as suffering from diabetes
- BISP completed and sent out

2.7.3 Indicators at national level

2.7.3.1 Structure

- Pharmacist training course promotion
- Pharmacies involved in secondary diabetes prevention
- Pharmacists with BISP

2.7.3.2 Process

- Leaflets handed out to customers with suspected undiagnosed diabetes
- Pharmacists trained
- Customers with suspected diabetes referred
- Pharmacists who complete BISP

2.7.3.3 Outcome

- Referred customers who return to the pharmacy diagnosed with diabetes.



2.7.4 Indicators at international level

2.7.4.1 Structure

- EuroPharm Forum country members involved in diabetes care at secondary diabetes prevention

2.7.4.2 Process

- Involved countries using BISP.

2.7.4.3 Outcome

- EuroPharm Forum countries involved in diabetes secondary prevention that have identified customers with unknown diabetes.

2.8 Checklist for customers suspected of suffering from diabetes

2.8.1 Materials

- Leaflets on diabetes and its complications
- Blood glucose measuring kit (device, strips) (if allowed)
- Recording forms, for pharmacy and national pharmacist's intervention evaluation
- Model letter to refer suspected customers to the physician
- European registration form (BISP)

2.8.2 Questioning technique

This should follow the questioning technique in Guideline 1.

In addition, questions should address diabetes signs/symptoms, according to the customer's complaints:

- What are the signs/symptoms?
- For how long have they been present?
- How frequent are the symptoms?
- How often has blood glucose been tested?
- When was the last blood glucose test performed and what was the value?

2.8.3 Blood glucose evaluation

For those customers who ask for blood glucose evaluation in the pharmacy, or those with diabetes signs/symptoms for whom the pharmacist recommends the test (if allowed):

- Customers are referred if the blood glucose result raises suspicion of diabetes
- Blood glucose values are assessed in accordance with WHO reference values
- The blood glucose value and test conditions are recorded in a card given to the customer

2.8.4 Referral

Customers with suspected diabetes are referred to the physician with a letter explaining the reasons for referral, asking for clinical and laboratory assessment.

A proposed model letter is in Annex 15.

2.8.5 Customers return to the pharmacy

Customers who were referred to the physician should be asked to return to the pharmacy to provide information about the doctor's diagnosis, and the pharmacist should record the results of the doctor's consultation.

2.8.6 Documentation

The pharmacist should document the mentioned indicators.

Each structure, process and outcome for customer, pharmacy, national and international level has to be documented.

For instance:

- All the suspected customers referred
- Suspected customers referred by signs/symptoms
- Suspected customers referred by hyperglycaemia

From those customers who were referred, document those:

- Who return to the pharmacy after the doctor's consultation
- Who have been diagnosed by the doctor as having type 2 diabetes

For those diagnosed as having diabetes, document prescribed treatment (drugs, nutrition care, exercise) and self-monitoring³ methods (blood/urine glucose), and other relevant information in the patient medication record (PMR).

2.8.6.1 BISP

The BISP should be completed for each customer suspected of suffering from unknown diabetes and referred. The BISP should be sent out immediately after having been completed.



3 Guideline 3: Guideline for outcome oriented patient counselling, information/education

PharmaDiaß services at this level of action are addressed to pharmacy customers with diabetes, mainly type 2.

The intervention is carried out by trained pharmacists.

3.1 Background information

Once diabetes is diagnosed, the patient should learn about:

- Diabetes and its late complications
- Drug treatment and immediate complications
- Nutrition care
- Physical activity and the benefits of metabolic control
- Self-monitoring³
- Foot care
- Maintaining a good quality of life and wellbeing

Each person with diabetes should be able to manage the disease to maintain normal glycaemia, HbA_{1c} as low as possible (≤ 8), without hypoglycaemia episodes, to delay the development of late complications.

3.2 Objectives

The objectives of this procedure are to ensure:

3.2.1 Pharmaceutical care (PhC) for patients with diabetes

PhC should address the following:

- Systematic identification and assessment of drug-related problems (DRPs)
- Choosing and implementing the best solution for DRPs, in cooperation with the patient and physician
- Ensuring the individual patient's understanding of the use and effects of their medication
- Follow-up of the patient and responding to any new problems

3.2.2 Information and education for patients with diabetes (and caregivers)

Examples of subjects about which information is needed:

- Purpose, technique, interpretation and actions to be taken for blood or urine glucose self-monitoring³
- Purpose and benefits of nutrition care for maintenance of normoglycaemia

- Purpose, benefits and goals of physical activity
- Purpose of good hygiene (mouth, foot)
- Purpose and benefits of foot care and foot surveillance
- Purpose of regular visits to the doctor
- Patients' rights and duties
- Benefits of belonging to Diabetes Association
- Purpose and benefits of identifying and solving DRPs

3.2.3 Patient concordance to drug therapy and other diabetes care

To achieve patient compliance with drug therapy and other diabetes care, the pharmacist needs to get patient concordance about:

- Drug therapy
- Self-monitoring³
- Nutrition care
- Foot surveillance
- Physical activity
- Weight control
- Self-medication as advised by pharmacist

3.3 Scope

The services under this procedure are targeted to pharmacy customers with diabetes, mainly type 2 diabetes.

The procedure covers the following areas of pharmacy services:

- Informing patients about diabetes, its complications and treatment benefits
- Educating people with diabetes (and caregivers) about drug treatment
- Educating people with diabetes (and caregivers) about nutrition care
- Educating people with diabetes (and caregivers) about the self-monitoring³ process – how to do it, when, for what, how to interpret and what action to take in the light of the results
- Educating people with diabetes (and caregivers) about need for physical activity
- Educating people with diabetes (and caregivers) about foot care and self-surveillance¹
- Educating people with diabetes about hypoglycaemia prevention, early detection and treatment

3.4 Process

Diabetes patients should be chosen according to established priorities and patient needs, which can be, for example:

- Presence of diabetes complications
- Metabolic decompensation
- Frequent hypoglycaemia episodes
- Non-compliance with the treatment or/and self-monitoring³ process
- Unhealthy nutrition



Patients can also be referred to the pharmacy services from general practitioners. Local guidelines can be set up for referrals.

3.5 Responsibilities

In each country the Pharmacy Association should be responsible for implementing, carrying out and supporting pharmacist's activities concerning diabetes care.

The pharmacist is responsible for:

- Using appropriate communication skills when advising patients
- Using appropriate questioning technique during the consultation to facilitate the gathering of accurate, comprehensive and relevant information
- Giving information/education materials to support verbal advice/information given
- Developing an active and positive collaborative relationship with all those who participate
- Developing and maintaining Protocols for the service
- Documenting the service
- Organising, implementing and marketing the service
- Documenting and structuring care activities

3.6 Structure and requirements

3.6.1 Pharmacist has undergone appropriate training in diabetes

See Protocol 7.3. for pharmacist training course programme.

Pharmacist training should include the intervention documentation.

3.6.2 Quiet area

Each pharmacy integrated in PharmaDiaß should organize the pharmacy so that there is a quiet, private area for customer or patient consultation.

3.6.3 Patient leaflets

Patient leaflets are more useful if they deal with one theme relevant to the patient's need. The proposed themes are:

- Pharmacy services for diabetes
- Diabetes and its complications
- Healthy nutrition for people with diabetes
- Benefits of physical activity
- Hypoglycaemia: signs, symptoms, detection, treatment and prevention
- Self-medication
- Self-monitoring³
- Foot care

When informing or teaching the patient, each subject can be accompanied with a leaflet.

3.6.4 Patient information/education programme

An individualized information/education programme should be drawn up for each patient.

3.6.5 Marketing the pharmacy services on diabetes care

Each pharmacy has to use appropriate marketing to promote the service to their customers.

It is recommended that the Pharmacy Association creates a poster for pharmacy service identification to be used at national level.

3.7 Documentation

To document the pharmacist's intervention and outcome, appropriate indicators and forms should be used.

3.7.1 Indicators at patient level

3.7.1.1 Structure

- Patient's receptivity.

3.7.1.2 Process

- Written patient consent
- Responding to the structured questionnaire to evaluate patient knowledge and compliance.

3.7.1.3 Outcome

Intermediate outcomes should be considered:

- Patient satisfaction with pharmacist's intervention
- Increase in patient wellbeing score (Annex 18)
- Reduction in number of hypoglycaemia episodes
- HbA1C reduction;
- Compliance with:
 - Drug treatment
 - Self-surveillance¹
 - Nutrition care
 - Foot care
 - Physical exercise



3.7.2 Indicators at pharmacy level

3.7.2.1 Structure

Existence of:

- Patient medication record (PMR) forms
- Wellbeing form
- Patient leaflets
- Model letter to refer the patient (Annex 16)
- Model of written patient consent for diabetes care
- Quiet area in the pharmacy for patient consultation
- BISP

3.7.2.2 Process

- Use of patient medication record (PMR) (Annex 14);
- Use of WHO wellbeing questionnaire
- BISP completed and sent out
- Focus on DRP existence and resolution
- Patient information/education, about:
 - Drug therapy
 - Nutrition care
 - Self-surveillance¹
 - Foot care
 - Physical activity
 - Hypoglycaemia
 - Diabetes Association benefits
- Minimum of 5 patients under diabetes care, per pharmacy

3.7.2.3 Intermediate outcome

- Patients under diabetes care with increase in wellbeing score (Annex 18)
- Patients under diabetes care with reduction in HbA₁C
- Patients under diabetes care with reduction in hypoglycaemia episodes
- Patients under diabetes care compliant with:
 - Drug therapy
 - Nutrition care
 - Self-surveillance¹
 - Foot care
 - Physical activity
 - Member of Diabetes Association

3.7.3 Indicators at national level

3.7.3.1 Structure

The existence of:

- Training course on diabetes care for pharmacists
- Data collection system using BISP
- Patient leaflets

3.7.3.2 Process

- Pharmacies involved in diabetes care at 3rd level
- Pharmacies evaluate patient's wellbeing (Annex 18)
- Pharmacies use BISP to document the intervention
- Pharmacies focus on drug-related problems (DRPs)
- Pharmacies focus on patient's information/education, about:
 - Drug therapy
 - Nutrition care
 - Self-surveillance¹
 - Foot care
 - Physical activity
 - Hypoglycaemia
 - Diabetes Association benefits
- All the pharmacists follow up a minimum of 5 patients

3.7.3.3 Intermediate outcome

- Patients with increase in wellbeing score
- Patients with reduction in HbA1C
- Patients well informed and educated about:
 - Drug therapy
 - Nutrition care
 - Self-surveillance¹
 - Foot care
 - Physical activity
 - Hypoglycaemia
- New members of a Diabetes Association, and those already members

3.7.4 Indicators at international level

3.7.4.1 Structure

- EuroPharm Forum country members involved in diabetes care at tertiary diabetes prevention
- Countries using BISP to document the intervention



3.7.4.2 Process

- Countries using and sending BISP to WHO to aggregate the data.

3.7.4.3 Intermediate outcome

- Each year, PharmaDiaß should be evaluated, based on BISP, and the aggregate data should be published
- Results of the aggregate data should show:
 - Patients with increase in wellbeing score (Annex 18)
 - Patients with reduction in HbA1C
 - Patients well informed/educated about:
 - Drug therapy
 - Nutrition care
 - Self-surveillance¹
 - Foot care
 - Physical activity
 - Hypoglycaemia
- Patients that have become members of a Diabetes Association

3.8 Checklists for outcome oriented patient counselling, information and education

The process of outcome oriented counselling, information/education of diabetic patients can be described in 10 steps:

Step 1 – Respond to “alarm” signals

Step 2 – Identify, assess and categorize patient for drug-related problems (DRPs)

Step 3 – Set targets and choose the best solution in cooperation with the patient and the doctor and implement this

Step 4 – Follow-up on targets and document the results

Step 5 – Evaluate patient’s knowledge about: disease, nutrition, hypoglycaemia, exercise, self-monitoring³, hygiene, drug therapy, self-medication

Step 6 – Give verbal information/education

Step 7 – Deliver patient leaflets

Step 8 – Assess patient’s compliance with drug therapy, nutrition care, self-monitoring³, and other issues

Step 9 – Assess patient’s metabolic control

Step 10 – Refer patient, as necessary

3.8.1 Step 1 – Respond to alarm signals

Alarm signals are indicators of problems which require further assessment. They can be related to the patient, the prescription or the therapy.

Examples of patient-related alarm signals:

- Symptoms (repeated infections, hypoglycaemia episodes, allergies, etc.)
- Dislike medication
- Dislike posology
- Fear of side effects
- Unknown medication benefits
- Problems with insulin administration
- Problems with self-monitoring³
- Lack of knowledge
- Real or imagined side effects
- Real or potential interactions
- OTC medication taken without indication or contraindicated
- Non-compliance with any prescribed therapy or recommendations
- Concern about the cost of the medication and self-monitoring³ material

Examples of prescription-generated problem alarm signals

- Inappropriate:
 - Drug
 - Strength
 - Dosage form
 - Treatment interval
 - Treatment duration
- Potential interactions
- Contraindications
- Lack of patient information about prescribed medication
- Lack of patient information about self-monitoring³

Examples of therapy-generated problem alarm signals

- Complaints of side effects
- Complaints about lack of effect
- Symptoms of adverse drug reactions
- Identification of drug interactions

Documentation

To be able to determine whether the alarm signals indicate DRPs it is necessary to collect data from the patient.

The relevant data can be collected by using appropriate questioning technique.

3.8.2 Step 2 – Identify, assess and categorize patient for DRPs

Having confirmed that the alarm signal is a sign of a drug-related problem, the next step is to decide the nature and extent of the problem. The relevant data can be collected using appropriate questioning technique. Data should be collected about the patient's medication history.



The assessment of the problem includes evaluation of subjective and objective data that support the nature and extent of the DRP.

The next step is to categorize the problem into one or more of the following classes:

- Lack of drug (patient condition not being treated)
- Unnecessary drug (patient does not need the medication he or she is taking)
- Improper drug selection (the patient is taking the wrong drug)
- Wrong dosage (too high or too low)
- Adverse drug reaction (the patient has a medical problem induced by the medication)
- Drug interaction (the patient has a problem related to drug interaction)
- Failure to take medication (patient cannot afford to purchase the drug)

Documentation

The DRPs are categorized to help the identification of the most frequent problems in diabetic patients.

3.8.3 Step 3 – Set targets and choose the best solution in cooperation with the patient and the doctor and implement it

Based on the analysis of DRPs, it is possible to suggest solutions to the problems.

In order to do this, it is important to agree the goal for the pharmacist and for the patient. The patient's drug related needs (DRNs) and the pharmacist's goals cannot be assumed to be the same. A patient with poorly controlled diabetes could, for instance, have one main target different from that of the pharmacist, which is to maintain metabolic control. It is essential to agree on a common goal for action to get desirable results.

Examples of solutions:

- Change medication
- Change posology
- Give instructions for self-monitoring³
- Give instructions for insulin administration
- Give patient information/education on diabetes and its complications
- Give instructions on how to avoid drug interactions and side effects
- Refer to the physician

Documentation

Documentation of the pharmacist's goals for solving DRPs and the patient's DRNs allow evaluation of the agreement between pharmacist and patient on the best method of solving the identified DRP.

3.8.4 Step 4 – Follow-up on targets and document the results

One of the key elements of the Pharmaceutical Care process is the ongoing follow-up of drug therapy and outcome.

The follow-up can be done when the patient comes to the pharmacy, but it is desirable to establish a regular consultation with the pharmacist. A monthly consultation is recommended (Annex 17).

- How has your diabetes been since the last conversation?
- Have you been taking the medicine?
- How do you feel the medicine is helping you?
- Have you been following self-monitoring³?
- Did you notice any drug side effects?

Documentation

The process and outcome of patient consultation can be documented in the recording form for patient outcome monitoring.

3.8.5 Step 5 – Evaluate patient’s knowledge about disease, nutrition, hypoglycaemia, exercise, self-monitoring, hygiene, drug therapy and self-medication

For diabetes to be metabolically controlled, the patient has to know and to comply with diabetes treatment (drug and non drug treatment) and to self-monitor the illness.

People with diabetes have to know the benefits and how to:

- Take prescription drugs
- Treat minor illness
- Self-monitor the disease
- Take physical exercise
- Care about hygiene
- Identify, treat and prevent hypoglycaemia episodes
- Care about nutrition
- Reduce, maintain or increase weight, according to need
- Care for feet
- Belong to a Diabetic Association

Information can also be collected by asking the patient about subjects he or she should know about for diabetes management, for example:

- Drug therapy
- Nutrition care
- Foot care
- Hypoglycaemia (prevention, identification and treatment)
- Hygiene
- Physical activity



- When to consult a doctor
- Patient rights and duties

And to demonstrate:

- Self-monitoring³ technique, evaluation of the results, recording and interpretation
- Insulin administration

Documentation

Patient's knowledge and compliance should be recorded and evaluated, so that the pharmacist's information and education can be appropriately targeted in each consultation.

3.8.6 Step 6 – Give verbal information/education

The pharmacist should tailor verbal patient information/education according to the knowledge that the patient needs to get diabetes under metabolic control.

The information/education should focus on the areas that the patient needs to know, but will mainly concern drug therapy.

Documentation

The area of verbal information should be recorded, to identify the themes most often dealt with.

3.8.7 Step 7 – Deliver patient leaflets

Verbal information should be complemented by written information using patient leaflets.

Patient leaflets should focus on the verbal information given in the consultation.

When handing out the leaflets, the patient's attention should be drawn to important details.

Documentation

The number of leaflets handed out and the different themes should be documented.

3.8.8 Step 8 – Assess patient's compliance with drug therapy, nutrition care, self-monitoring, and other issues

3.8.8.1 Drug therapy

- Diabetes medicines use: oral antidiabetic drugs and/or insulin
- Patient's medication record (PMR) use
- Protocols on self-medication for patients with diabetes

- **Medicines use and self-medication**

For antidiabetic drugs, protocols should be drawn up for the safe and proper use of drugs. The protocols should include drug interactions, time to take medicines, posology control, side effects, etc.

Self-medication protocols should be drawn up on the safe treatment of minor illness in diabetic patients.

- **Patient Medication Record**

The patient medication record (PMR) (Annex 14) is a register of patient data, updated every time the patient comes into the pharmacy. It contains:

- Patient identification
- Sociodemographic data
- Analytical data
- Therapeutic data (prescription and non prescription drugs)

The PMR allows the pharmacist to check for:

- Contraindicated drugs
- Non-compliance
- Duplicated therapy (drugs from the same pharmacological group)
- Inappropriate drug therapy
- Inappropriate dosage
- Drug use without indication
- Allergies

3.8.8.2 Self-monitoring³

People with diabetes need to self-monitor blood or urine glucose levels and to adapt therapy, food intake and exercise according to the glucose level and the prescription.

For accurate blood or urine self-monitoring,³ the patient has to be informed, trained and educated.

The education of the patient and caregivers includes:

- Benefits of self-monitoring³
- Material needed
- How to use blood/urine glucose tests
- When to use blood/urine glucose tests
- How to record measurements in a diary
- How to interpret the results
- How to manage therapy, nutrition and physical activity to maintain normal blood or urine glucose



Patient education, information and training process

In accordance with the doctor's recommendations, education and information, the pharmacists should inform and educate patients about:

a. How to use blood glucose devices and strips

Explain the technique to the patient and ask him or her to demonstrate the method they use to evaluate blood glucose. Give advice, as necessary.

b. When to take readings

The patient has to be aware of the importance of following the doctor's recommendations about when and how often to take the measurements.

c. How to record blood glucose values in the patient diary

Immediately after the measurement is taken, the patient should record the test value. It should be recorded according to the physician instructions and the kind of diary used. Normally, the value, date and time of the test is recorded, together with the conditions relating to food intake.

d. How to interpret the results

The patient should be trained and educated on:

What is being measured — the concentration of glucose in the blood/urine

Why measuring — to evaluate if diabetes is metabolically controlled

What does the result mean — if the level is normal, high or low

e. How to respond to changes

All patients with diabetes should know that blood glucose values are constantly changing according to food intake and physical exercise. Depending on the test result, the patient may need to change food intake and physical activity.

For type 1 diabetes, the amount of insulin injected should be adjusted according to the self-monitoring³ results.

Offer the patient written information/education material about self-monitoring³.

f. Patient's facilities to buy the medicines and self-monitoring³ material

In some countries, diabetic patients have economic facilities (e.g. reimbursement, free supplies) to buy medicines and self-monitoring³ material and they should know their rights and benefits. The pharmacist should inform patients about the facilities they are entitled to.

3.8.9 Step 9 – Assess patient’s metabolic control

Based on self-monitoring³ data, hypoglycaemic episodes and HbA₁C levels, the patient’s metabolic control is evaluated. When metabolic control is not achieved, reinforcement of the patient’s information/education and/or referral to the physician is recommended.

3.8.10 Step 10 – Refer patient

When the pharmacist recognizes that the patient needs medical assessment, special instructions or therapy adjustment, the patient should be advised to seek an appointment.

The pharmacist should call the doctor or, if this is not possible, should write a message informing the doctor of the reasons why the patient has been advised to consult.

The written message to the doctor can be done using a model letter (Annex 16).

Examples of situations when the patient should be referred to the doctor include:

- Non-compliance with drug therapy
- Non-compliance with nutrition recommendations
- Non-compliance with self-monitoring³ tests
- Foot complications
- Signs of infections
- Side effects of prescribed drugs
- Drug interactions
- Metabolic decompensation
- Contraindicated drugs
- Drug need



4 Guideline 4: Guideline for Basic Information Sheet for the Pharmacist (BISP)

4.1 Background information

The quality of care promoted by the pharmacist can be measured and assessed using a data collection system at European level, called the Basic Information Sheet for Pharmacist (BISP).

BISP allows aggregation of data and benchmarking.

The analysis of the data allows the characterization of the pharmacist's intervention in each country.

4.2 BISP

The BISP is a tool to evaluate the pharmacist's intervention at European level in secondary and tertiary diabetes prevention.

The completed BISP can be sent directly to the WHO Regional Office for Europe or through the Pharmacy Association in each country.

The methodology used depends on each country's organization and the decision of the pharmacist task force.

To evaluate the pharmacist's diabetes tertiary prevention, a BISP should be completed once a year for each patient. It should be completed the first time the patient comes to the pharmacy each year.

The time the pharmacist spent in patient consultation should be recorded, in order to evaluate the feasibility of pharmacist involvement in diabetes care in pharmacy practice.

To avoid problems of confidentiality, BISP does not include the patient's name.

Each year, an evaluation should be carried out of the completed BISPs sent to WHO.





BISP PharmaDiaβ Care

Basic Information Sheet for Pharmacist
St. Vincent Declaration Implementation

For patients with diabetes or suspected cases. To be filled once a year per patient with last year data

1 Pharmacy Data	Do you have in your pharmacy devices for: Blood glucose? <input type="checkbox"/> Height? <input type="checkbox"/> Weight? <input type="checkbox"/> BP ? <input type="checkbox"/>
------------------------	--

2 Consumer /Patient Data	Sex <input type="radio"/> F <input type="radio"/> M Day/Month/Year Birth date // Weight _____ kg Height _____ cm
---------------------------------	---

Only for those suspected of having diabetes

3 Suspected People	By signs or symptoms By hyperglycaemia in the pharmacy Please register the data: ≥ 110 to <126 mg/dL (≥ 6.1 to < 7 mmol/L) – 8 hours fast ≥ 126 mg/dL (≥ 7 mmol/L) – 8 hours fast ≥ 200 mg/dL (≥ 11.1 mmol/L) – 2 hours after meals	Referred to the doctor Y N Date // Diabetes confirmed Y N Date //
---------------------------	--	--

Patients with diabetes only

4 Medical Diagnosis	Type 1 Type 2 Other Known duration (years) <input type="checkbox"/> <5 <input type="checkbox"/> 5–10 <input type="checkbox"/> 11–15 <input type="checkbox"/> >15	Hypertension Y N <input type="checkbox"/> <input type="checkbox"/> CVD <input type="checkbox"/> <input type="checkbox"/>
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5 Prescribed therapy and other patients' data	You may choose more than one	Compliance	Yes	No	Wellbeing score	
	1. Diet <input type="checkbox"/> 2. Insulin <input type="checkbox"/> 3. Biguanides class <input type="checkbox"/> 4. Sulphonylureas class <input type="checkbox"/> 5. α-glucosidase inhibitors <input type="checkbox"/> 6. Meglitinide class <input type="checkbox"/> 7. Thiazolidinedione class <input type="checkbox"/> 8. Others <input type="checkbox"/>	1. <input type="checkbox"/> <input type="checkbox"/> 2. <input type="checkbox"/> <input type="checkbox"/> 3. <input type="checkbox"/> <input type="checkbox"/> 4. <input type="checkbox"/> <input type="checkbox"/> 5. <input type="checkbox"/> <input type="checkbox"/> 6. <input type="checkbox"/> <input type="checkbox"/> 7. <input type="checkbox"/> <input type="checkbox"/> 8. <input type="checkbox"/> <input type="checkbox"/>				Smoker Y N <input type="checkbox"/> <input type="checkbox"/> Hypoglycaemia episodes Frequent <input type="checkbox"/> Rare <input type="checkbox"/> None <input type="checkbox"/>
Drug Related Problems (DRP)	Did you find any DRP? (You may choose more than one)	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	If Yes – solution by
	1. Drug use without indication <input type="checkbox"/> 2. Duplicated therapy <input type="checkbox"/> 3. Drug need but not prescribed <input type="checkbox"/> 4. Drug interaction <input type="checkbox"/> 5. Contraindicated drug <input type="checkbox"/> 6. Inappropriate dosage <input type="checkbox"/> 7. Side effects of drugs <input type="checkbox"/>					Pharmacist Referral <input type="checkbox"/> <input type="checkbox"/>



6 Clinical Analysis	Hb A _{1c} = _____%	Albuminuria/Microalbuminuria _____%
	No data <input type="checkbox"/>	No data <input type="checkbox"/>

7 Self- surveil- lance and compliance	Doctor's recommendations (you may choose more than one):	Done as recommended:		
		Always	Sometimes	Never
	Self-monitoring of glycaemia <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Self-monitoring of glycosuria <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Nutrition care <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Foot Care <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Weight Control <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8 Pharma- cist's interven- tion	Did you keep patient medication record (PMR) in the Pharmacy? Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you evaluate: Blood glucose <input type="checkbox"/> BP <input type="checkbox"/> Body Weight <input type="checkbox"/> BMI <input type="checkbox"/>
	Did you evaluate drug compliance? Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you take any action to improve drug compliance? Yes <input type="checkbox"/> No <input type="checkbox"/>

9 Patient's Education and Information	Did you inform/educate patient about:											
		V	W	N		V	W	N		V	W	N
	Drug therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Drug related problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Technique and			
	Insulin inj Techn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Weight control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	devices			for
	Self medication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Foot care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	glycaemia/glycosuria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Smoking cessation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Physical exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Hypoglycaemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				Nutrition care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Diab. Assoc. benefits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	verbal (V), written (W) or no (N) information											

Time spent in consultation min

CVD – Cardiovascular disease Y – Yes N – No

BP – Blood Pressure F – Female M – Male

DRP – Drug Related Problem



4.3 Objectives

There are two main objectives of the BISP:

- a. To have the same data collection system at European level for pharmacist's intervention so that data can be aggregated
- b. To evaluate the European pharmacist's intervention at secondary and tertiary diabetes prevention to increase the quality of care

4.4 Secondary diabetes prevention

Section 3 of the BISP is to be completed when the pharmacist suspects that a customer is suffering from undiagnosed diabetes.

The pharmacist should refer the customer to his or her doctor for a full assessment. The customer should be asked to return to the pharmacy, to inform the pharmacist of the results of the doctor's evaluation.

One BISP should be completed and sent to the WHO Regional Office for Europe for each customer referred.

The sections that need to be completed for this level are Sections 1, 2 and 3.

4.5 Tertiary diabetes prevention

Patient follow-up is needed to prevent immediate and late diabetes complications, because uncontrolled metabolic disease is the cause of severe and irreversible complications.

As diabetes is almost asymptomatic, the patient has to be followed up for compliance with drug therapy and the additional care need for metabolic control, namely nutrition care, exercise, weight control and self-monitoring.³

The pharmacist has to explain to the patient why therapy is needed and should continue informing/educating the patient to achieve the compliance required for metabolic control.

Details are recorded of the patient, their drug therapy, compliance, some risk factors (smoking), diabetes complications (CVD, hypertension, hypoglycaemia episodes) and other measurements such as HbA₁C and albuminuria.

Data related to the pharmacist's intervention in identification and resolution of DRPs, patient information/education and measures to improve drug compliance and care are also recorded.

The sections that need to be completed for this level are Sections 1, 2, 4, 5, 6, 7, 8 and 9.

The BISP is completed once a year for each patient and is completed the first time the patient comes to the pharmacy in each year.

4.6 Progress with pharmacist's intervention

As care of patients with diabetes involves a multidisciplinary approach, the patient outcome is the result of several interventions, so it is impossible to define the exact benefits from the pharmacist's intervention.

According to SVD, the main goals for diabetes care are to reduce diabetes complications through a multidisciplinary approach.

Comparing data from each year's intervention, some indicators can be evaluated and their progression monitored.

- Wellbeing score
- Smoking
- Frequency of hypoglycaemia episodes
- DRP occurrence
- HbA_{1c}
- Albuminuria/microalbuminuria
- Drug compliance
- Compliance with self-monitoring³ process
- Patient information/education

4.7 BISP completion

4.7.1 General

- Sections 1 and 2** should always be completed, ie, for people with suspected diabetes and for patients with diabetes.
- Section 3**
 - To be completed once, for each person
 - To be completed just for those with suspected diabetes. Ask those referred to return to the pharmacy to report on the diagnosis.
- Sections 4, 5, 6, 7, 8 and 9**
 - To be completed for patients with diabetes
 - To be completed once a year per patient
 - To be completed the first time the patient comes to the pharmacy in each year
- Cross (X) over the square or write over it – Do not write outside the square

4.7.2 Specific

Section 1 – Pharmacy data

These data are considered as PharmaDia β indicators at the pharmacy level.

You should insert a cross (X) over the square if you have the device in your pharmacy.



Section 2 – Consumer data

Register the birth date, according to the day, month and year. For day and month with one digit, you should insert a zero in the left square.

For sex, put an X over the letter F (female) or M (male).

Insert weight in kg and height in cm.

Section 3 – Suspected diabetes

To be completed just for those suspected of having diabetes.

Indicate (with an X) whether your suspicions relate to signs, symptoms or hyperglycaemia measured in the pharmacy.

If the suspicion was based on hyperglycaemia, you should put an X over the square that corresponds to the level measured. You should also record with an X whether the analysis was carried out at fasting or post-prandial conditions.

You should record whether or not you advised the consumer to see the doctor, with an X over the appropriate square, and the date.

When the consumer returns to the pharmacy with the doctor's evaluation, you should record the date and if the suspicion was or was not confirmed, ie, if the consumer was diagnosed as having diabetes.

Section 4 – Medical diagnosis

For persons with diabetes.

In this section you register the diabetes type, how long the patient has had the diagnosis, and if the patient has hypertension or another cardiovascular disease. The recording is made with an X over the appropriate square.

Section 5 – Prescribed therapy and other patient's data

You should record with an X over the appropriate square according to the patient's treatment. Then you record the patient compliance.

Record if the patient is or is not a smoker.

The wellbeing score should also be included. For that evaluation you have to use the wellbeing test (self-administered) and calculate the score.

Record the frequency of hypoglycaemia episodes reported by the patient.

Record whether you identified any drug-related problems (DRPs) and their nature.

If the identified DRPs are not mentioned, fill in the nearest square.

Record whether DRPs were solved by the pharmacist or whether you referred the patient to the doctor.

Section 6 – Clinical analysis

To complete this section you should ask the patient to bring their last analysis of HbA_{1c} and albuminuria. If the patient has no data, put an X over the appropriate square.

Section 7 – Self-monitoring³ and compliance

You should record if the doctor recommended the different mentioned self-monitoring³ methods.

Then record patient compliance with this (always, sometimes or never), with an X over the appropriate square.

Section 8 – For the pharmacist intervention

These are some PharmaDiaß indicators. You should record if you kept the patient medication record (PMR) in the pharmacy, and if you measured the blood glucose, blood pressure or body weight.

The record is made by putting an X over the appropriate square.

Record whether you evaluated drug compliance and any action taken to improve it.

Section 9 – Individual patient education and information

The patient information and education can be verbal, written or both. It should be registered with X over the square V (verbal), W (written), or both accordingly. In case that no information is given, the cross (X) should be put over the square N (no given information).



Key Indicators

Key indicators are the minimal indicators to be used for evaluation of PharmaDiaß, at each level of action.

Note that:

1. Patient data – should be collected by the pharmacist, in the pharmacy
2. Pharmacy data – should be collected by pharmacist
3. National data – should be collected by task force member in each country or by the person responsible for running the Programme, based on each pharmacist's data
4. International data or European data – should be collected by the task force manager, based on each country's data, sent by the task force member.

Guideline 1 – Key indicators

A – At customer level

1. Customer receptive
2. Responding to a structured questionnaire
3. Healthy lifestyle followed

B – At pharmacy level

1. Availability of:
 - a) Standard structured questionnaire
 - b) Weight measuring device
2. BMI evaluation
3. Customers identified as having any diabetes risk factors
4. Customer's agreement to change risk factors.

C – At national level

1. Pharmacies involved in diabetes primary prevention
2. Customer leaflets on diabetes handed out
3. Type of diabetes risk factors identified:
 - a) Obesity
 - b) Physical inactivity
 - c) Unhealthy nutrition

D – At European level

1. Countries involved in diabetes primary prevention
2. Countries with customer leaflets on diabetes
3. Countries involved in diabetes primary prevention
4. Countries that identified customers with modifiable diabetes risk factors



Guideline 2 – Key indicators

A – At customer level

1. Customer receptive
2. Responding to a structured questionnaire
3. Customer's commitment to return to the pharmacy after seeing the doctor

B – At pharmacy level

1. Availability of:
 - a) Standard structured questionnaire
 - b) Weight measuring device
2. BMI evaluated
3. Customers identified as having diabetes signs/symptoms

C – At national level

1. Pharmacies involved in diabetes secondary prevention
2. Customers with suspected diabetes referred
3. Referred customers who return to the pharmacy, diagnosed with diabetes

D – At European level

1. Countries involved in diabetes secondary prevention
2. Countries that identified customers with suspected unknown diabetes
3. Cases of unknown diabetes diagnosed by the doctor

Guideline 3 – Key indicators

A – At patient level

1. Patient receptive
2. Patient with HbA1C reduction
3. Patient's compliance with drug treatment
4. Patient's compliance with self-surveillance

B – At pharmacy level

1. Availability of patient leaflets
2. DRPs identified and solved
3. Patients with HbA1C reduction
4. Patients under diabetes care

C – At national level

1. Availability of patient leaflets
2. Pharmacies involved in diabetes tertiary prevention
3. Pharmacies focusing on DRPs
4. Patients followed up
5. Patients with HbA1C reduction
6. Patients who became members of a Diabetes Association

D – At European level

1. Countries involved in diabetes tertiary prevention
2. Countries focusing on DRPs
3. Countries with patients' HbA1C reduction



Annex 2

Guideline 1: Evaluation form at customer level

Fill in one form per customer.

It should be filled in under the pharmacist's responsibility.

(a) Date __/__/__

Form 1.1

	AT CUSTOMER LEVEL	YES	NO	PARTLY
(b)	Structure: <ul style="list-style-type: none">• Customer receptive			
(c)	Process: <ul style="list-style-type: none">• Responding to the structured questionnaire			
(d)	Outcome: <ul style="list-style-type: none">• Customer's satisfaction• Healthy lifestyle followed			

(a) Fill in date of the pharmacy intervention

(b) (c) (d) Fill with an X for each item if yes, no or partly



Guideline 1: Evaluation form at pharmacy level

One form should be filled in for each pharmacy, under the pharmacist's responsibility. This form can be filled in every month, every 2 months, or even once a year, depending on practical issues or country recommendations.

(a) From ___/___/___ to ___/___/___

Form 1.2

AT PHARMACY LEVEL		A	B
(b) Structure: Available in the pharmacy:	<ul style="list-style-type: none"> • Standard structured questionnaire; • Weight measuring device; • BMI table; • Customer leaflets; • Registration forms; • Trained pharmacy staff. 	YES	NO
(c) Process – with how many customers did you:	<ul style="list-style-type: none"> • Use structured questionnaire; • Measure body weight; • Calculate BMI; • Hand out diabetes leaflet; • Record the intervention. 	N°	Total n°
(d) Outcome – how many pharmacy customers were:	<ul style="list-style-type: none"> • Identified as having any diabetes risk factor; • Type of risk factor identified: Obesity; Physical inactivity; Unhealthy nutrition. 	N°	Total n°
(e)	<ul style="list-style-type: none"> • Type of verbal advice given: Obesity; Physical inactivity; Unhealthy nutrition. • Customer's agreement to change risk factors; • Customer's adoption of lifestyle to change risk factors. 	YES	NO

- (a) Record the start and finish dates.
- (b) Record with an X whether or not the mentioned tools are present in pharmacy (yes or no).
- (c) A – Record the number of customers in whom you used the mentioned tools;
B – Record the total number of customers subject to the pharmacist's intervention (diabetes prevention).
- (d) A – Record the number of pharmacy customers who were identified with the mentioned risk factors.
B – Record the total number of customers who were subject to pharmacy staff intervention (diabetes prevention).
- (e) Record with an X if the response is yes or no for the respective items.

Guideline 1: Evaluation form at country level

Fill in one form per country, each year.

It should be filled in by the task force manager in each country.

(a) From __/__/__ to __/__/__

Form 1.3

AT NATIONAL LEVEL		A	B
(b)	Structure: <ul style="list-style-type: none"> • Pharmacies involved in diabetes primary prevention; • Pharmacy staff trained. 	N°	Total n° of pharmacies
(c)	Process: <ul style="list-style-type: none"> • Leaflets handed out to customers with known diabetes risk factors. 	N°	Total n° of printed leaflets
(d)	Outcome: <ul style="list-style-type: none"> • Type of diabetes risk factors identified: <ul style="list-style-type: none"> Obesity; Physical inactivity; Unhealthy nutrition. • Type of advice/information given: <ul style="list-style-type: none"> Obesity; Physical inactivity; Unhealthy nutrition. • Customers who adopted lifestyles to change diabetes risk factors. <ul style="list-style-type: none"> Obesity; Physical inactivity; Unhealthy nutrition. 		Total n°

- (a) Record the start and finish dates.
- (b) A – Record the number of pharmacies involved in diabetes prevention;
B – Record the total number of pharmacies which, according to the country pharmacy organization, could be involved in diabetes prevention.
- (c) A – Record the sum of the leaflets handed out in all the pharmacies involved in diabetes prevention;
B – Record the total number of printed leaflets
- (d) A – Record, according to each item, the number of diabetes risk factors identified, advice given and customers that changed lifestyles, by all the country pharmacies involved
B – Record the total number of customers subject to the intervention on diabetes prevention, according to each item.



**Guideline 1:
Evaluation form at EuroPharm Forum (European) level**

Fill in one form each year.

It should be filled in by the task force manager on Diabetes Care at EuroPharm Forum, based on countries' data.

(a) From ___/___/___ to ___/___/___

Form 1.4

AT EUROPEAN LEVEL		A	B
(b)	Structure: <ul style="list-style-type: none"> • Involved countries with customer's leaflet on diabetes; • Involved countries with pharmacy staff training courses. 	N°	N° of country members
(c)	Process: <ul style="list-style-type: none"> • EuroPharm Forum countries involved in diabetes primary prevention. 		
(d)	Outcome <ul style="list-style-type: none"> • EuroPharm Forum country members that identified customers with modifiable diabetes risk factors: <ul style="list-style-type: none"> • Obesity; • Physical inactivity; • Unhealthy nutrition. 		

- (a) Record the start and finish dates (1-year interval).
- (b) A – Record the number of countries with diabetes leaflets and with pharmacy staff training courses, which are involved in primary diabetes prevention;
B – Record the total number of EuroPharm Forum country members.
- (c) A – Record the number of countries involved in primary diabetes prevention;
B – Record the total number of EuroPharm Forum country members.
- (d) A – Record the number of EuroPharm Forum country members which identified customers with the mentioned diabetes risk factors;
B – Record the total population in the involved country members.



Annex 6

Guideline 2: Evaluation form at customer level

Fill in one form per customer.

It should be filled in under the pharmacist's responsibility.

(a) Date __/__/__

Form 2.1.

	AT CUSTOMER LEVEL	YES	NO	PARTLY
(b)	Structure: <ul style="list-style-type: none">• Customer receptive.			
(c)	Process: <ul style="list-style-type: none">• Responding to the structured questionnaire.			
(d)	Outcome: <ul style="list-style-type: none">• Customer's satisfaction;• Customer's commitment to return to the pharmacy after seeing the doctor.			

(a) Fill in date of the pharmacy intervention.

(b) (c) (d) Fill with an X for each item if yes, no or partly.



**Guideline 2:
Evaluation form at pharmacy level**

One form should be filled in for each pharmacy, under the pharmacists' responsibility. This form can be filled in every month, every 2 months, or even once a year, depending on practical issues or country recommendations.

(a) From ___/___/___ to ___/___/___

Form 2.2

AT PHARMACY LEVEL		A	B
(b)	Structure: Available in the pharmacy:	YES	NO
	<ul style="list-style-type: none"> • Standard structured questionnaire; • Weight measuring device; • BMI table; • Customer leaflets; • Record forms; • Model letter to the doctor; • BISP. 		
(c)	Process – with how many customers did you:	N°	Total n°
	<ul style="list-style-type: none"> • Use structured questionnaire; • Measure body weight; • Calculate BMI; • Hand out diabetes leaflet; • Record the intervention. 		
(d)	Outcome – how many pharmacy customers were:	N°	Total n°
	<ul style="list-style-type: none"> • Identified as having diabetes signs/symptoms; • In agreement to be referred to the doctor; • Diagnosed by the doctor as having diabetes; • BISP filled in and sent to EuroPharm Forum. 		

- (a) Record the start and finish dates.
- (b) Record with an X whether or not the mentioned tools are present in pharmacy (yes or no).
- (c) A – Record the number of pharmacy customers who were identified with the mentioned risk factors;
B – Record the total number of customers who were subject to the pharmacists' intervention to identify those with unknown diabetes.
- (d) A – Record the number of customers, according to each item;
B – Record the total number of customers who were subject to the pharmacists' intervention to identify those with unknown diabetes.

Guideline 2: Evaluation form at country level

Fill in one form per country, each year.

It should be filled in by the task force manager in each country.

(a) From ___/___/___ to ___/___/___

Form 2.3

AT NATIONAL LEVEL		A	B
(b)	Structure: <ul style="list-style-type: none"> • Pharmacies involved in diabetes secondary prevention; • Pharmacies with BISP. 	N°	Total n°
(c)	Process: <ul style="list-style-type: none"> • (1) Customer leaflets handed out to the customers with suspected undiagnosed diabetes; • (2) Pharmacists trained; • (3) Customers with suspected diabetes referred; • (4) Filled in BISP. 		
(d)	Outcome: <ul style="list-style-type: none"> • Referred customers who return to the pharmacy, diagnosed with diabetes. 		

- (a) Record the start and finish dates.
- (b) A – Record the number of pharmacies, for each item;
B – Record the total number of pharmacies which, according to the country pharmacy organization, could be involved in diabetes secondary prevention.
- (c) Record the global (all the involved pharmacies) number of each item and the global target population, in each country.
- (1) A – Total n° of leaflets handed out in all pharmacies involved to customers suspected as having unknown diabetes;
B – Total n° of printed leaflets.
- (2) A – Total n° of trained pharmacists;
B – Total n° of pharmacists which, according to the pharmacy organization, could be trained.
- (3) A – N° of customers suspected as having unknown diabetes referred (sum of all the involved pharmacies);
B – N° of population to whom the involved pharmacies cover (e.g. 1 pharmacy/5000 persons; 2 pharmacies/10 000 persons).
- (4) A – The total number of BISP filled in all the involved pharmacies;
B – N° of customers with suspected unknown diabetes referred (in all the involved pharmacies).
- (d) A – Sum of referred customers (in all the involved pharmacists) who return to the pharmacy with a diagnosis of diabetes;
B – Sum of the referred customers [(c)(3)A].



**Guideline 2:
Evaluation form at EuroPharm Forum (European) level**

Fill in one form each year.

It should be filled in by the task force manager on Diabetes Care at EuroPharm Forum, based on countries' data.

(a) From ___/___/___ to ___/___/___

Form 2.4

AT EUROPEAN LEVEL		A	B
(b)	Structure: <ul style="list-style-type: none"> EuroPharm Forum countries involved in diabetes secondary prevention. 	N°	N° of country members
(c)	Process: <ul style="list-style-type: none"> Countries using BISP. 		
(d)	Outcome: <ul style="list-style-type: none"> EuroPharm Forum countries involved in diabetes secondary prevention that have identified customers with unknown diabetes confirmed by the doctor; Cases of unknown diabetes diagnosed by the doctor. 		

- (a) Record the start and the finish dates (1-year interval).
- (b) A – Record the number of countries involved in diabetes secondary prevention;
B – Record the EuroPharm Forum country members.
- (c) A – Record the number of country members using BISP;
B – Record the number of country members involved in diabetes secondary prevention.
- (d) A – Record the country members in which the pharmacist identified customers with unknown diabetes, confirmed by the doctor and the total number of cases of diabetes identified in the involved countries;
B – N° of country members involved in secondary diabetes prevention and the total population which the involved pharmacies cover (e.g., 1 pharmacy/5000 persons).



Guideline 3: Evaluation form at patient level

Fill in one form per patient.

It should be filled in under the pharmacist's responsibility.

(a) Date __/__/__

Form 3.1

	AT PATIENT LEVEL	YES	NO	PARTLY
(b)	Structure: <ul style="list-style-type: none">• Patient receptive.			
(c)	Process: <ul style="list-style-type: none">• Written patient consent signed;• Responding to the structured questionnaire to evaluate patient knowledge and compliance.			
(d)	Outcome: <ul style="list-style-type: none">• Patient satisfaction;• Increase in patient wellbeing score;• Reduction in number of hypoglycaemia episodes;• HbA1C reduction;• Compliance with:<ul style="list-style-type: none">• Drug treatment;• Self-surveillance¹;• Nutrition care;• Foot care;• Physical exercise.			

(a) Fill in date of the pharmacy intervention.

(b) (c) (d) Fill with a X in each item if yes, no or partly.



Guideline 3: Evaluation form at pharmacy level

One form should be filled in for each pharmacy, under the pharmacists' responsibility. This form can be filled every month, every 2 months, or even once a year, depending on practical issues or country recommendations.

(a) From ___/___/___ to ___/___/___

Form 3.2

AT PHARMACY LEVEL		A	B
(b) Structure: Existence of:	<ul style="list-style-type: none"> • Patient leaflets; • Model letter to refer the patient; • Quiet area in the pharmacy for patient consultation; • BISP. 	YES	NO
(c) Process – with how many patients did you:	<ul style="list-style-type: none"> • Use Patient Medication Record (PMR); • Use WHO Wellbeing questionnaire; • Fill in and send out BISP; • Identify and solve DRP; • Inform/educate, about: <ul style="list-style-type: none"> • Drug therapy; • Nutrition care; • Self-surveillance¹; • Foot care; • Physical activity; • Hypoglycaemia; • Diabetes Association benefits; • Have under diabetes care. 	N°	Total N°
(d) Intermediate outcome – how many patients:	<ul style="list-style-type: none"> • With increase in wellbeing score; • With reduction in HbA_{1C}; • With reduction in the number of hypoglycaemia episodes; • Compliant with: <ul style="list-style-type: none"> • Drug therapy; • Nutrition care; • Self-surveillance¹; • Foot care; • Physical activity; • Member of Diabetes Association. 	N°	Total N°

- (a) Record the start and finish dates.
- (b) Record with an X whether or not the mentioned tools are available in the pharmacy.
- (c) A – Record the number of number of times each item was followed in the pharmacy;
B – Record the total number of patients subject to diabetes information/education.
- (d) A – Record the number of times each item was obtained;
B – Record the total number of times you evaluated each item.



Guideline 3: Evaluation form at country level

Fill in one form per country, each year.

It should be filled in by the task force manager in each country.

(a) From ___/___/___ to ___/___/___

Form 3.3

AT NATIONAL LEVEL		A	B
(b)	Structure: Existence of: <ul style="list-style-type: none"> • Training course on diabetes care for pharmacists; • Data collection system using BISP; • Patient leaflets. 	YES	NO
(c)	Process: pharmacies involved <ul style="list-style-type: none"> • In diabetes care at tertiary prevention level; • Evaluating patient's wellbeing; • Using BISP; • Focusing on drug related problems (DRP); • In patient information/education about: <ul style="list-style-type: none"> • Drug therapy; • Nutrition care; • Self-surveillance¹; • Foot care; • Physical activity; • Hypoglycaemia; • Diabetes Association benefits; • Patient follow-up by all the pharmacists. 	N°	Total n°
(d)	Intermediate outcome – how many patients: <ul style="list-style-type: none"> • With increase in wellbeing score; • With reduction in HbA₁C; • Well informed and educated about: <ul style="list-style-type: none"> • Drug therapy; • Nutrition care; • Self-surveillance¹; • Foot care; • Physical activity; • Hypoglycaemia; • Became members of a Diabetes Association. 	N°	Total n°

(a) Record the start and finish dates.

(b) Record with a X the existence or non existence of the mentioned tools.

(c) A – For each item, record the number of pharmacies involved;

B – Record the number of pharmacists which, according to the country pharmacy organization, could be involved (total or just members of the Association).

(d) A – Record, for each item, the number of patients (sum of those of all the involved pharmacies);

B – Record, for each item, the number of patients subject to education and information, in all the involved pharmacies.



Guideline 3: Evaluation form at EuroPharm Forum (European) level

Fill in one form each year.

It should be filled in by the task force manager on Diabetes Care at EuroPharm Forum, based on countries' data.

(a) From ___/___/___ to ___/___/___

Form 3.4

AT EUROPEAN LEVEL		A	B
(b)	Structure: <ul style="list-style-type: none"> • EuroPharm Forum country members, involved in diabetes care, at tertiary diabetes prevention; • Involved countries using BISP to document the intervention. 	N°	N° of country members
(c)	Process: <ul style="list-style-type: none"> • Countries using BISP and sending it to WHO to aggregate the data. 		
(d)	Intermediate outcome: <ul style="list-style-type: none"> • Each year, PharmaDiaβ is evaluated using BISP and the aggregated data are published; • Results of the aggregated data should show: <ul style="list-style-type: none"> • Patients with increase in wellbeing score (%); • Patients with reduction in HbA₁C (%); • Patients with reduction in BP (%); • Patients well informed/educated about: <ul style="list-style-type: none"> • Drug therapy; • Nutrition care; • Self-surveillance¹; • Foot care; • Physical activity; • Hypoglycaemia; • Patients that have become members of a Diabetes Association. 	YES	NO

- (a) Record the start and finish dates.
- (b) A – Record the number of countries involved in patient information and education and using BISP;
B – Record the total EuroPharm Forum country members.
- (c) A – Record the number of countries that are using BISP and sending it to aggregate data;
B – Record the total EuroPharm Forum country members.
- (d) Record yes or no, to each item. In those items with (%), just record if you have data.



Annex 14

Patient Medication Record

The patient medication record (PMR) contains patient data that the pharmacist gets from the patient interview, to evaluate a patient's drug related problems (DRPs). The aim is to collect information about personal information, family medical history, patient knowledge about diabetes and its treatment, allergies and other health related problems, drug therapy, metabolic data and patient wellbeing.

Patient's name _____
Date of birth ____/____/____ Diabetes since _____ (year)
Address _____

Tel. _____
Doctor _____ GP/Sp Tel. _____

Diabetes in the family (which member(s)) _____

Early cardiovascular disease in the family Yes

Diabetes type 1 2 Other _____

Diabetes complications existence Which _____

Allergies to: _____

Smoking

Alcohol intake

Height _____ m

Weight _____ Kg

Prescribed self-monitoring³:

Glycaemia

Glycosuria

Body weight

Foot

Other: _____

Sp – Specialist on diabetes

GP – General practitioner



Model letter to refer customers with diabetes signs/symptoms

Dear Doctor,

Mr/Mrs is a client of my pharmacy
..... (tel.:) and he/she came to
me to:

- Buy a medicine for.....
- Complain of diabetes symptoms.....
- Present diabetes signs.....
- Test his/her blood glucose level, which was higher than normal

I expect you would like to assess him/her for possible unknown diabetes.

Thank you in advance for your attention,

The Pharmacist



Model letter for referring the patient

Date/...../.....

Mr./Mrs
(patient's name)

Referred from Pharmacy
(pharmacy's name)

Tel Pharmacist's name

Patient information:

Diabetes

Other:

Allergies:

.....

Drug therapy:

Drug	Brand Name	Strength	Posology	Observations

Reason for referral:

- Non-compliance with drug therapy
- Non-compliance with nutrition care
- Non-compliance with self monitoring glycaemia/glycosuria
- Foot complications
- Frequent hypoglycaemia symptoms
- Infection signs/symptoms
- Cardiovascular disease signs/symptoms
- Neurological disease signs/symptoms
- Drug interactions
- Side effects of drugs
- Contraindications
- Metabolic decompensation
- Others

We ask for your attention to this patient, particularly concerning the aspects mentioned above.



Patient outcome monitoring form

Patient name _____

Since the last visit to the pharmacy, patient experienced:

Date of the visit						
1. Symptoms						
Hypoglycaemia episodes treated by others						
Occasional hypoglycaemia episodes						
Frequent hypoglycaemia episodes						
Weight maintenance						
Weight gain						
Weight lost						
Foot injuries						
Increased diuresis						
Infectious disease						
Disease in bed						
Disease with absent from work						
Disease with hospitalization						
2. Self-monitoring³						
Hyperglycaemia most of the time						
Hyperglycaemia once a day						
Hyperglycaemia occasionally						
3. Self-monitoring³ technique:						
Very good						
Regular						
Bad						

4. Self-monitoring ³ registration:						
Always						
Sometimes						
Never						
5. Self-monitoring ³ interpretation:						
Well						
Bad						
6. Self-surveillance ¹ compliance						
Foot care						
Weight control						
Glycaemia/glycosuria						
Others						
7. Drug related problems						
Lack of drug (patient condition without treatment)						
Unnecessary drug						
Improper drug selection						
Wrong dosage						
Adverse drug reaction						
Drug interaction						
Failure to take medication						



WHO (Five) Wellbeing Index (1998 version)

According to the WHO European Regional Office, the Project's evaluation should include patient wellbeing evaluation. This is included in the Basic Information Sheet for Pharmacists (BISP).

To get this score, the patient has to fill the Wellbeing Questionnaire. It is a self-administered questionnaire.

So, the questionnaire should be translated and validated to each language.

The validation methodology for the translation is as follows:

1. From the English questionnaire, it should be translated it into each national language. The sentences should be correct in each language.
2. Then it should be given to 5–6 persons, who know English very well, to translate it into English.
3. They shouldn't be health professionals.
4. Then, it should be evaluated to see if the translations have the same meaning as the English original.
5. If so, this means that your translation is according to the original and it may be used.

WHO (Five) Wellbeing Index (1998 version)

Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better wellbeing.

Example: if you have felt *cheerful and in good spirits more than half of the time during the last two weeks*, put a tick in the box with the number 3 in the upper right corner.

Over the last two weeks Some of the time	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
I feel cheerful and in good spirits	5	4	3	2	1	0
I feel calm and relaxed	5	4	3	2	1	0
I feel active and vigorous	5	4	3	2	1	0
I wake up feeling fresh and rested	5	4	3	2	1	0
My daily life is filled with things that interest me	5	4	3	2	1	0

Scoring:

The *raw score* is calculated by totalling the figures of the five answers. The raw score ranges from 0 to 25, 0 representing worst possible and 25 representing best possible quality of life.

To obtain a *percentage score* ranging from 0 to 100, the raw score is multiplied by 4. A percentage score of 0 represents worst possible, whereas a score of 100 represents best possible quality of life.

Interpretation:

It is recommended to administer the Major Depression (ICD-10) Inventory if the raw score is below 13 or if the patient has answered 0 to 1 to any of the five items. A score below 13 indicates poor wellbeing and is an indication for testing for depression under ICD-10.

Monitoring change:

In order to monitor possible changes in wellbeing, the percentage score is used. A 10% difference indicates a significant change (ref. John Ware, 1995).

Wellbeing score:

It is desirable that persons with diabetes have, at least, 12 as score for the self-administered wellbeing questionnaire.



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