Establishment of indicators monitoring diabetes mellitus and its morbidity

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Prepared by: **EUDIP group**

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Chapter 1

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Chapter 1
1. SUMMARY

The objective of this project is to provide a set of indicators with a definition of the underlying data collection to monitor diabetes mellitus and its outcome in the Member States/EFTA on a routine, consistent and uniform basis.

Diabetes mellitus and its complications have become a major public health problem in all countries. It causes significant physical and psychological morbidity, disability and premature mortality among those affected and imposes a heavy financial burden on health services. The prevalence of diabetes is rising globally, and the number affected is expected to double by 2010. The prevalence and complications can be reduced through early and appropriate intervention. Within Europe, important differences between potential risk factors (lifestyle, environmental factors, genetic predisposition etc) exist.

The EUPHIN-HIEMS database aims at the establishment of Community health indicators, offering the possibility to monitor health in various aspects, among which the occurrence and consequences of diabetes mellitus.

Although diabetes has been identified as one of the leading and growing contributors to the global disease burden, so far no relevant and reliable indicators are available, based on comparable data collection, throughout the EU to monitor diabetes and its outcome.

An inventory of available indicators and data sources in the different EU/EFTA countries has been established. Focussing on different aspects of diabetes mellitus requiring surveillance, further potential indicators and alternative data collection have been added to the inventory. From this list a set of indicators has been be selected, based on relevance, validity, sensitivity, reproducibility and responsiveness. Data source/data collection is described. A pilot study has been done to evaluate feasibility and to provide an initial data set in the different EU countries.

Finally, a set of core and secondary indicators are proposed to monitor diabetes and its sequel in EU/EFTA countries.

EUDIP GROUP 2000

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2. INTRODUCTION

The European Union has launched a Program of Community Action on Health Monitoring in order to obtain comparative information on the health of the population in the different member states.

The Objectives of the Health Monitoring Program are

→ To measure health status trends and determinants throughout the community
→ To facilitate planning, monitoring and evaluation of community programs and action
→ To provide Member States with appropriate health information to make comparisons and support their national health policies.

The Program supports projects evaluating/improving data collection systems as well as morbidity specific projects.

EUDIP (European Union Diabetes Indicators Project) has the objective to propose a set of indicators to monitor diabetes mellitus and its outcome in the Members States/EFTA countries on a routine, consistent and uniform basis.
Nominated/invited national representatives of the EU/EFTA Member States have participated in the preparation of the inventory of indicators and its final selection as described in this report (table 1).

For the **selection of the indicators,** several quality criteria applied:

→ Relevance (it should provide relevant information on the disease)
→ Validity (it should represent the reality)
→ Comparability (it should be comparable or it should in the future be possible to be comparable between countries or regions)
→ Reproducibility and sensitivity (it should be sensitive to changes over time and place)
→ Feasibility (whether or not the indicators will be available within the near future in most of the countries).

The nominator as well as the denominator are discussed.

3. Organisation and management

The project is a collaborative effort of the different national representatives, in collaboration with their national centres. Initially, all EU/EFTA countries signed their agreement to participate. However, due to lack of time and/or other priorities several representatives had to withdraw during the project.
End 2000 a list with possible indicators was circulated by email/mail to all formal participants. Everybody was invited to add and/or remove items from this list.
In the first months of the project it became clear that two participants who originally signed for the project, withdrew from it. They represented the countries Denmark and Iceland. Unfortunately it has been impossible for them and for the coordinator of the project to replace them.

In **March 2001** the core group met in Brussels to perform a first analysis of the submitted list/items. A questionnaire including the proposed items, considered being essential for monitoring diabetes and its complications was prepared. This list was resubmitted by mail/email to the group, with the question to indicate which indicators on the list were available in the different member states and to prepare a presentation for the meeting in May 2001.

In **May 2001** the whole group met for the first time in Paris. Presentations of available data sources and data were discussed. Different items were taken into consideration: their importance, reliability, availability and feasibility.
A report and more detailed questionnaire was prepared and circulated.

In **June 2001** the core group met again in Brussels to discuss the questionnaire, which should be resubmitted to the group. After a second round of comments in the summer, the revised questionnaire was submitted to the whole group in the autumn of 2001 (annex 1).

In **November 2001** the core group met in Holland to discuss the first data submission and data analysis, which would be finished end of December.

In **January 2002** the core group met in Paris to discuss further data analysis and prepare the report for the whole group meeting. Problems and pitfalls were discussed. Data analysis was planned.

In **March 2002** the whole group met in Luxembourg. The results were presented to the group. A selection of indicators was proposed together with their collection and source. The report and data presentation were discussed as well as a proposal for further data collection. Data submitted so far were to be double checked and where possible completed. This revision should have taken place before the summer but due to various reasons was completed in several countries later than foreseen. Crude death rates, linked to diabetes were to be submitted for central analysis in Helsinki KTL (Professor Antti Reunanen).

In **May 2002** Dr Kristian Midthjell participated in the HIS/HES meeting on behalf of the EUDIP group.
The report was submitted to the group in **October 2002.**

Final report will be submitted November 2002.

4. DESCRIPTION OF THE DISEASE: DIABETES MELLITUS

Diabetes mellitus is a chronic disease, characterised by hyperglycaemia, resulting from defects in insulin secretion, insulin action or both. Definition of diagnosis of diabetes mellitus according to WHO is the presence of classical symptoms including polyuria, polydipsia and unexplained weight loss,   and/or a hyperglycaemia $\geq$ 11.1 mmol/l (200 mg/dl) in a random sample or
   fasting (no caloric intake for $\geq$ 8hrs) plasma glucose $\geq$ 7,0 mmol/l (126 mg/dl) and/or
   postprandial value $\geq$ 11.1 mmol/l (200 mg/dl) (2 hrs plasma glucose level during an oral glucose tolerance test.) This test should be performed as described by WHO, using a glucose load containing the equivalent of 75 h anhydrous glucose dissolved in water.)
In the absence of unequivocal hyperglycaemia with acute metabolic decompensation, these criteria should be confirmed by repeat testing on a different day. (1)

Impaired glucose tolerance or impaired fasting plasma glucose (IGT/IFG) refers to an metabolic state between the normal and diabetic one. This population is at increased risk to develop diabetes mellitus and cardiovascular disease, however does not fulfil the daignostic criteria of diabetes mellitus.
Definition of impaired fasting plasma glucose is a fasting glucose value $\geq$ 6,1 mmol/l (110 mg/dl) and $\leq$ 7 mmol/l (126 mg/dl).
Definition of impaired glucose tolerance is a 2 hrs postprandial glucose level $\geq$ 7,7 mmol/l (140 mg/dl) and $\leq$ 11,1 mmol/l (200 mg/dl).

Persisting hyperglycaemia can and - in most situations -will lead to long term damage and failure of different organs, especially the eyes, kidneys, vessels, nerves and heart. Different forms of diabetes mellitus are identified depending on their aetiology. The two most important forms are type 1 or immune mediated diabetes mellitus and type 2 or insulin resistance mediated diabetes mellitus.
More rare forms include genetic defects of β cell function, genetic defects in insulin action, exocrine pancreas pathologies, and endocrinopathies.
In this report type 1 and 2 diabetes mellitus are included, since they represent the majority of the diabetic population.

Immune mediated or Type 1 diabetes is characterised by a cellular mediated destruction of the pancreatic ß cells. In a variable time period it will lead to an absolute deficiency of insulin production. In general, it is diagnosed in childhood, although a second peak is observed at a more advanced age (2-3). A classical triad of symptoms: polyuria, polydipsia and weight loss, usually leads to the diagnosis and insulin treatment. Insulin injection therapy is the only adequate therapy for this form of diabetes.

Type 1 diabetes mellitus is characterised by a genetic susceptibility for environmental factors, which causes an autoimmune destruction of insulin producing cells. HLA linkage has been described (4).

Different autoimmune markers exist at diagnosis in more than 80% of the newly diagnosed cases (5).

Many previous and actual research programs (Eurodiab Ace, Biomed) are aiming at the discovery of possible further genetic and environmental risk factors (6-8).

Type 2 diabetes is characterised initially by insulin resistance with a relative insulin deficiency. In time, it may modify to a predominantly secretory defect of the pancreatic β cells. Clinical symptoms may not always be present at onset and in some cases the diagnosis will only be made at the discovery of late complications.

Overweight/obesity is a major risk factor for type 2 diabetes (9). It causes insulin resistance, which will lead eventually to type 2 diabetes. With age the risk of hyperglycaemia increases. Diet and/or physical exercise will modify insulin resistance, improving insulin sensitivity and thus normalising blood glucose. If no normalisation of blood glucose levels is obtained through weight loss (dieting), oral hypoglycaemic medication will be introduced. Only if that therapy fails as well to normalise blood glucose values, insulin treatment will be started.

Although risk factors for the development of type 1 and type 2 diabetes are different, long term complications (macro and/or micro angiopathy) present a major risk to both groups.

Longitudinal studies clearly demonstrate the relationship between ischemic heart disease, stroke, gangrene, lower limb amputation and diabetes. This relationship still persists, even when one has controlled for other risk factors as smoking, dyslipidemia, hypertension and obesity (10-11).

Micro vascular complications of diabetes, causing retinopathy and blindness, terminal renal failure, necessitating dialysis and transplantation, as well as neuropathy have been known for a long time

(12-13). Prevention and/or delay in the progression of complications have been observed when applying an intensive treatment with self-monitoring.

Changes in lifestyle and nutritional habits contribute to an improved metabolic control and result in a significant reduction in type 2 diabetes.

The global prevalence of diabetes mellitus is increasing and estimated to rise from 135 million in 1995 to 300 million by 2025 (14). These estimations include both diagnosed and an estimate of undiagnosed cases of diabetes.

With more surveillance of persons with diabetes, the full extent of the individual burden for society becomes apparent, putting diabetes in the first line of public health threats. This will cause an increasing financial burden on health services. Sedentary life style, changed eating habits, environmental factors and genetic predisposition are all considered potential risk factors for type 2 diabetes. Progression of overweight and obesity in younger age groups (WHO estimate over 22 million children < 5 yrs are overweight) is a major contributor as well.

At the intermediate phase (IFP, IGT), prevention of type 2 diabetes disease still is possible. At different levels, intervention programs can change progression and outcome in a positive way. With respect to society, lifestyle changes in persons at risk can be effective. Early diagnosis and intensive treatment of the persons who have the disease will lead to a reduced prevalence of complications, and improve long-term prognosis.

Discussing the economic impact of intensifying treatment, a short-term increase in costs should be expected. However, in the long run a reduction in expenditures can be forecasted due to a decrease in complications with their enormous human and financial costs. (15-17)

Due to limited resources public health choices have to be made with respect to what action can be planned.

In spite of increasing knowledge and the intensive research on the impact of different risk factors, within Europe no comparable indicators are available to monitor the different aspects/presence of diabetes and its morbidity. The aim of this project is to propose comparable indicators for diabetes and its morbidity in EU/EFTA

countries, to evaluate the impact of the different therapeutical approaches in Europe, and plan further improvement.

Diabetes Mellitus in EUROPE

5.1 Indicator selection

In order to select a set of indicators, monitoring diabetes mellitus and its sequels, initially an exhaustive list of indicators has been established. Existing international, multinational as well as regional data sources (WHO, ADA, OECD, UK national diabetes framework, MONICA, DIABCARE etc.) have been used. Indicators on socio-economy, demography, gender and ethnicity as defined in the ECHI 1 report are included.

Finally, four disease specific categories have been identified. The burden of the disease and its complications as well as possible modifiable risk factors offering possible prevention have been included.

I.   **Risk factors for diabetes mellitus**
II.   **Epidemiology of diabetes mellitus**
III.   **Risk factors for diabetes complications**
IV.   **Epidemiology of diabetes complications**

Evaluation of the public health importance within the public health perspective, availability of data in the short and in the long term, and data sources have been discussed extensively. A final shortlist of indicators and sources has been established. Core indicators are available in most EU/EFTA countries and/or are otherwise considered to be of such importance that they should be made available within a short time span.

Second indicators are considered important, but are not yet available in most EU/EFTA countries and will need time to be implemented.

It is evident this shortlist is neither exhaustive nor final. Flexibility is necessary in order to include recent scientific developments, changes of policy and better technology.

5.2 Data Source description

The following data sources are identified for the different indicators.

5a. Surveys
Health Interview/Examination Survey (HIS/HES).
Through surveys representative information can be obtained on health and health related topics. They are essential components of national/international health monitoring. Health Surveys in the EU:HIS/HES evaluations and models (project...) provides an overview of what is going on in EU/EFTA countries as well as world wide. They analysed different existing surveys, and compared frequently and rarely discussed topics. Differences between the surveys as well as problems in comparability for some subjects (heavy drinking and smoking) were observed, leading to the following recommendations.

- Surveys should use national population based samples
- They should recur in specific intervals (thus not single wave) and
- They should include the whole population (not a specific age/gender/ethnicity)
- They should provide information on different parameters (not be limited to 1 subset like e.g. CVD- HES).

Health Interview Surveys are based on the self reported information provided by the participant, whereas Health Examination Surveys include self-reported information in combination with validated information through physical examination and blood analysis.
For both surveys, different questions with respect to this project have been defined and will be included in the respective section.
Detailed methodology has been described in the HIS/HES HMP.
A representative sample will be taken in the different EU/EFTA countries. Sampling should be every 3-5 years. This time interval is based on financial aspects, the time necessary for the collection, analysis of data and the development of possible intervention programs.
A questionnaire as well as detailed description on how to perform different medical or paramedical acts are provided in the HES project report. This HIS/HES project phase 2 (HMP Health surveys in the EU: HIS and HIS/HES evaluations and models, 01/09/2002) had the specific aims to select evaluate and recommend methods for use in HES and HIS/HES surveys and for future field-testing and development during phase 3. and to maintain and develop the health survey (HIS, HES and HIS/HES) database, to add new data and information on

existing recommendation and standards and to develop the system for dissemination.
For further details the reader is referred to the final report of this working group.

5b. Registries: Through regional or national registries many indicators are available providing information on a wide range of topics. Population structure trends (mortality and natality) life expectancy etc can be calculated through these registries. For specific diseases or therapeutic approaches, national disease specific registries have been created in several EU /EFTA countries offering the possibility of comparison between countries. Representativity for a specific population must be indicated.

5c. Diabetes Quality of Care Systems (DiabCare Systems)
End of the eighties, representatives of government health departments and patients' organisations from all EU countries met with diabetes experts under the aegis of WHO regional Offices for Europe and the European Region of the International Diabetes Federation (IDF), European region in St Vincent Italy. They unanimously agreed on the following recommendations and urged their implementation in all countries throughout Europe.

Diabetes mellitus is a major and growing European health problem, a problem at all ages and in all countries. It causes prolonged ill health and early death. It currently (1989) threatens at ten million European citizens. It is within the power of national governments and health departments to create conditions in which major reduction in this heavy burden of disease and death can be achieved. Countries should be given formal recognition to the diabetes problem and deploy resources for its solution. Plans for the prevention, identification and treatment of diabetes and particularly its complications- blindness, renal failure, gangrene and amputation aggravated heart disease and stroke, - should be formulated at local, national and European levels. Investments now will earn great dividends in reduction of human misery and in massive savings of human and material resources.

General goals and 5yr targets should be achieved by the Organised activities of the medical services in active partnership with diabetic citizens, their families, friends and workmates.

→*Management of their own diabetes and education for it*
→*Planning, provision and quality audit of health care*
→*National, regional and international organisations for disseminating information about health maintenance*
→*Promoting and applying research*

To implement these recommendations Diabetes Care Quality evaluation projects have developed programs and data collection systems at different levels (primary and secondary care (DiabCare). It is an ongoing collection of a number of indicators recorded in a basic information sheet, once yearly for every diabetes patient. It allows benchmarking by a DiabCare server as well as local analysis in a local data system. It includes a relatively complete set of indicators on clinical parameters for quality compared with golden standards available for the same parameter. The DiabCare data system provides an extremely interesting data source offering possibilities to monitor continuously according to internationally recognised criteria, diabetes care. Second advantage is the possibility to provide information back to healthcare provider and to the person with diabetes. Within the different countries, national and regional sheets have been developed and adjusted for the different health care providers. A set of core data could be forwarded annually towards a central EU institution (EUROSTAT?) providing comparisons on quality of care of Diabetic patients over Europe. (Several examples of data collection sheets are included in Annex 2a—x).
For the direct future, one has to keep in mind that DiabCare data collection was intended to rise the quality of diabetes care in local care centers, and **not** to provide robust epidemiological data.
Although it may offer over time the possibility to collect comparable data on diabetes mellitus indicators in EU/EFTA Countries, harmonisation of core data collection on regional level as well as national levels, will need further attention.

5d. Sentinel Practice Surveillance Network (SPSN)
In several EU countries primary care based sentinel practice surveillance networks have been established (EU project HMP). This network seeks to recruite clusters of motivated GP's (nationally and internationally) to perform surveys on different items. Among these items, diabetes prevalence and diabetes management have been

included. Participants are motivated and the standards are well defined. It would be feasible to obtain annual updates of diagnostic outcome indicators. SPSN are available in most EU countries.

However, their national representativity is not yet established. Furthermore, only primary care is included and mainly diagnoses are monitored. At this time point, SPSN is considered an interesting but no the optimal data source.

5e. Hospital Discharge Records

The main hospital discharge diagnosis is the condition identified as responsible for reimbursement of treatment and/or diagnostic procedures. The HDR covers almost the entire population, both sexes and all ages. National reimbursement systems based on Diagnosis Related Groups (DRG) are applied in all countries except Austria, Germany, UK and The Netherlands. The ninth revision of the ICD is used in Italy, The Netherlands, Portugal and Spain. The remaining countries use ICD 10.

Linkage with mortality is possible for Finland, The Netherlands, Sweden and the UK.

The "in hospital case fatality" rate is computed in all partner countries except Italy and Spain. In Finland the validation of the HDR is implemented: in other countries validation is not implemented (Austria, Germany, Italy, The Netherlands, Norway) or is performed by retrospective review (Sweden), considers only a population sample (France and Spain) or assigns a reliability score (arithmetic mean) to the Hospitals, based on the data quality (evaluation criterion) in conformity to three categories: A, B, C (pondered aspects of clinical codification, coherence of the internment data and the execution time sending data to the IGI (Portugal).

Data are generally accessible, with previous written request of authorisation, through national health or statistical institutions.

Another HMP Project 'Hospital Data Project (2000) aims to provide a detailed and practical methodology for the production of comparable hospital data. Differences in coding for primary and secondary diagnosis may be different and thus need attention. In some situations adding a specific diagnosis may increase reimbursement and therefore lead to an incorrect increase in that specific pathology. Often diabetes as second diagnosis is underreported.

Harmonisation of hospital data   in the EU/EFTA countries is of great importance and will ameliorate comparability of the data.

5.f Insurance/reimbursement structure (RS)

With the advances in technologies most reimbursement structures (insurances) are linked with specific national personal numbers. These numbers are unique either for enlarged data collection (see UNN) or just for the insurance. When encrypting these numbers, information on age, sex and linked medication, doctors visits and special diagnostic or therapeutical interventions, can be obtained in an anonymous and very reliable way. Some countries have many different insurance systems, completing this way of collecting data. This technique, although very reliable, has the disadvantage of neither providing any results (outcome indicators), nor to give any direct feedback to patient or health care provider. As validation it may prove a very good source.

5g. Drug registries

Previous studies have utilised national drug sales to estimate prevalence of different pathologies (e.g. diabetes mellitus). National annual drug sales are recorded in most countries and by applying the DDD (Defained Daily Dose) method, the prevalence of drug treated diabetes can e estimated. Disadvantage of this method is the variation in mean daily dose in different countries, resulting in a varying discrepancy towards the DDD. (34).

5h. Patient Associations

Through Collaboration with patient organisations in the past, incidence as well as prevalence numbers have been obtained with which primary sources have been validated. The active participation in the St
 Vincent declaration and its effects, indicate the possibilities as well as the importance of patient organisations. They may be implicated as validation source in some of the proposed indicators.

6. Indicator description

I. Risk factors for diabetes mellitus

When discussing risk factors for diabetes mellitus, the different subtypes - type 1 and type 2 diabetes - have to be separated.

For **type 1 diabetes** the genetic susceptibility for environmental riskfactors is considered to lead through autoimmune destruction of ß cells (in the pancreas) towards insulin deficiency. Actually a multitude of possible risk factors (early food intake, viral infections, toxins) have been identified, and are evaluated in more detail in prospective studies. For the moment, none of these riskfactors correspond yet to the criteria mentioned previously. Actual or future research may provide riskfactors which can be applied as indicator within the next decade. In that situation they should be integrated in this shortlist.

For **type 2 diabetes**, several risk factors have been identified.

Ia. Obesity is a major risk factor for type 2 diabetes. (18-19). As indicator for obesity, the percentage of persons in a population with a Body Mass Index (BMI) > 30 % has been used (cut off point based on recent WHO recommendation). The population should be stratified according to age, since with advancing age, prevalence of type 2 diabetes increases.
BMI can be obtained through surveys (HIS/HES). A major risk of HIS as data source for this indicator is underestimation of BMI (overestimation of height, underestimation of weight) and thus of the population at risk (20-21). This underestimation may not be identical in the different EU/EFTA countries. For national trend monitoring, HIS remains useful.
First choice data collection in the EU/EFTA countries should be through HES.
Several reports indicate the predictive value of Waist Hip Ratio for the development of type 2 diabetes mellitus. Other reports suggest a better relationship between insulin resistance and abdominal fat, waist circumference alone. Longitudinal studies are needed to prove whether waist circumference on itself is a better predictor for diabetes mellitus. However, for the moment, lack of standardised measurements and insufficient data make it impossible to include WHR at this stage.

Ib. Physical inactivity as an indicator of sedentary lifestyle, contributes to the development of type 2 diabetes, partly through increased risk for obesity. (22-23) Many different attempts to evaluate physical activity have been reported varying between the number of cars per population unit to very detailed questionnaires on daily life activities. In HIS and HES questions on physical (in) activity have been included. Therefore this indicator has not been discussed any further by the EUDIP group.

Ic. Nutritional habits will influence obesity. Increased saturated fat intake, increased protein intake as well as an important intake of fast acting carbohydrates will influence insulin resistance and contribute to the development of type 2 diabetes (24-26).
Several projects have been included in the HMP, evaluated different aspects of nutrition. National nutritional habits have been evaluated by different Dafne projects. Sjostrom and co-workers, discussing indicators on nutritional habits as well, have performed a recent HMP project. In the Euro HIS project, questions about food intake have been included, offering the possibility to evaluate this important aspect. It has been decided that through these projects the indicator is sufficiently covered and does not need to be re-evaluated within the framework of EUDIP.

Id. Gestational diabetes has been recently reported as a potential risk factor for the development of type 2 diabetes. So far, different approaches exist within EU /EFTA countries with respect to how and when gestational diabetes is diagnosed. This introduces a large variability in the prevalence of gestational diabetes, probably not based on real differences. To define the optimal timing for testing and to define diagnostic criteria was considered to be beyond the expertise of the EUDIP group. However, after harmonisation of the diagnostic criteria the contribution of this risk factor for type 2 diabetes in women should be re- evaluated and the prevalence of gestational diabetes possibly recommended on the shortlist of indicators (27-29)

II. Epidemiology of diabetes mellitus

IIa. Incidence of type 1 diabetes

The epidemiology of type 1 diabetes mellitus is monitored through its annual incidence in children between 0-14 years of age at diagnosis (clinical)calculated per 100.000 children. This indicator has been carefully evaluated through a previous pan EU program (30). In this program, methodology has been defined and tested and outcome in the different EU/EFTA states compared (31). Two data sources and a capture/ recapture analysis have been introduced. The age group between 0-14 yrs has been chosen to include the specific group of patients with type 1 diabetes mellitus. Gender and age at onset have been included in order to monitor trends and changes in age at onset.

IIb. Prevalence of diabetes mellitus

Point prevalence of diabetes mellitus (according to the definition of WHO, including type 1 and type 2 diabetes mellitus) per 1000 general population will provide information on the number of persons in whom diabetes has been diagnosed.

The American Diabetes Association expert committee has recently modified their diagnostic criteria for diabetes mellitus. For epidemiological studies, diabetes mellitus prevalence and incidence can be based on just fasting plasma values > 7.0 mmol/l. According to the new WHO criteria, fasting plasma values as well as the glucose tolerance test values can be used.

The aim of just including fasting values is to improve standardisation and to facilitate fieldwork, where Glucose tolerance testing may be difficult. Several groups have evaluated the influence of these modifications of the criteria on the target population. The group with normal fasting values, but increased postprandial values, may not be included in the diabetic population. They do represent a population at increased risk for macro vascular complications (32-33). Further observations are required before changing should be envisaged not including the postprandial hyperglycaemia levels, requires further evaluation prior to introduction.

Prevalence of diabetes mellitus will provide insight on the size of the problem and its evolution in time, taking gender and age into account. If possible, the whole population should be included. Minimally, the population between 25-64 yrs should be included.

Many different data collection systems exist in the EU/EFTA states

Harmonisation will be necessary to improve comparability.

One may offer the possibility to include the prevalence of persons with IGT, at high risk to progress to type 2 diabetes. (HES)

In the EURODIAB framework (EURODIAB C) an estimation of the prevalence of diabetes mellitus was made through drug sales. (34) Insulin and oral hypoglycaemic medication sales per year were used together with a mean dose per patient per day in order to calculate estimates of the prevalence. Surveys among General Practitioners and endocrinologists over a limited time were used to double-check the estimates. Through the first source, the persons with only diet are excluded. Furthermore, a Scottish report showed the difference between prescribed and used medication, which proved not identical at all.

In the Sentinel network, a HMP project using clearly defined subgroups of general practitioners in different MS, prevalence of diabetes was measured (35). National representativity of these groups as well as comparability between countries (including different health care approaches) needs further confirmation at this time point.

Drug sales as well as unique national number linked to diabetes, and reimbursement systems, may provide useful estimates of diabetes prevalence, excluding the diet only group. Not in all counties these numbers will be available

HIS will provide data on diabetes mellitus prevalence in those persons, who have been diagnosed with diabetes mellitus and the treatment they receive.

Through HES, not only diagnosed persons with diabetes mellitus, but also the group of persons with impaired fasting glucose metabolism would be detected through fasting plasma glucose measurement.

The best comparable data set will be obtained through HES, providing information on the prevalence of diabetes, linked to gender, age at onset, and socio-economic status.

III. RISK FACTORS FOR COMPLICATIONS OF DIABETES

The indicators in this chapter refer to persons with diabetes mellitus. Two groups of indicators are proposed: process and outcome indicators. Process indicators provide information on the frequency with which a certain test (lab/clinical examination etc.) is being performed and will be an indicator for the quality of care provided. Intensive treatment and early intervention have been demonstrated to improve long-term prognosis. Based on this, internationally accepted guidelines have been introduced. This may prevent deterioration and further progression of late complications.

Outcome indicators provide the result of this test and thus inform whether a certain risk factor is present or absent.

IIIa. Metabolic control

Achieving a good metabolic control is the primary goal of diabetes treatment. Many prospective studies demonstrate an association between a good metabolic control and a reduction in micro vascular (retinopathy, nephropathy neuropathy) and macro vascular (cardiovascular) complications (36-37).

Glycosylated haemoglobin (HbA1c) reflects metabolic control over the past 2-3 months. Persisting high blood sugar levels will result in an increased HbA1c. It takes about 2 to 3 months for the HbA1c to change again. In general, a control every 3 months would be informative. The minimum is once/twice yearly.

Process Indicator for glycaemic control is the percentage of persons with diabetes who have had a HbA1c control over the last 12 months. Outcome indicator for metabolic control is the percentage of persons with a measured HbA1c over the last 12 months, who have a value over 7.5%. Risk for micro and macro vascular complications increases with persistent hyperglycaemia. (38-40). The cut off of 7.5% is based on different prospective studies, showing a reduced risk for complications below 7.5 %.

Standardisation of HbA1c laboratory techniques is being discussed. When guidelines will be issued, their introduction should be considered. Until that time DCCT standard is considered to be the golden standard.

IIIb. Abnormal lipid profiles in patients with type 2 diabetes contribute to higher rates of cardiovascular complications.

Through dietary and therapeutic intervention, reduction of this risk can be obtained (40-43).

Process indicator proposed is the percentage of patients with lipid profile measured over the last 12 months. The lipid profile should include total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides.

Outcome indicator is the percentage of patients who have had a lipid profile tested and in whom the outcome is considered pathological total cholesterol >5 mmol/l
LDL>2.6 mmol/l
HDL <1.15 mmol/l
triglycerides >2.3 mmol/l

In the near future modifications may be proposed with respect to the therapeutic goals (lower/higher cut off limits). Longitudinal studies continue to analyse optimal cut off limits. Close evaluation of literature and recommendations of the scientific working groups are necessary.

IIIc. Presence of microalbuminuria has been identified as a risk factor for the development of renal and vascular complications.
It is defined as positive when the results are as follows:
24 hrs collection: > 30 mg/24 h: timed collection: $20\mu g/min$;
spot collection > 30 $\mu g/mg$ creatinine.
When it is detected, adequate therapeutic action can delay and/or stop progression towards further kidney failure or hypertension.
Process indicator proposed is the percentage of persons with diabetes who have had a urine check for the presence of microalbuminuria. For the moment different detection and urine collection methods as well as different cut off levels are used. For the purpose of this study, presence or absence of microalbuminuria as defined nationally or regionally will be included. Recommendations of expert taskforces should be included when available.

IIId. Presence of hypertension is an independent risk factor for the development of complications. It is an established risk factor for the development of macular edema and it is associated with proliferate retinopathy. (44-45)
Process indicator is the percentage of persons with diabetes who have had their blood pressure taken over the last 12 months.
Outcome indicator is the percentage of persons with diabetes who had their blood pressure taken and in whom systolic values ≥ 140 mm Hg and diastolic values ≥ 90 mmHg.

Cut off values are based on the WHO guidelines. In near future modifications may be proposed with respect to the therapeutic goals (lower/higher cut off limits). Close follow up of literature and recommendations of the scientific working groups are necessary.

IIIe. Smoking of persons with diabetes mellitus contributes to the development of cardiovascular complications. (46-47)
Indicator for smoking is the percentage of persons with diabetes who are smoking including cigars, cigarettes and pipe.
Convincing documentation has been provided on the negative causal effect smoking has on morbidity and mortality in the general population (cardiovascular morbidity, asthma, increased allergy, cancer). In the population of persons with diabetes mellitus an increased risk for the development of macro vascular as well as micro vascular complications has been demonstrated.

IIIf. Overweight and obesity are important risk factors contributing to the development of micro and macro vascular complications (48-50)
Indicator for overweight is the Percentage of persons with diabetes seen annually with a Body Mass Index (BMI) > 25 kg/m²
Indicator for obesity is the Percentage of persons with diabetes seen annually with a BMI > 30 kg/m²
Due to overweight and obesity, insulin resistance progresses. This increases risk for macro and micro vascular complications.
Annual height and weight measurement allows the calculation of these indicators should be measured once yearly this offers the possibility to calculate BMI in a reliable way.

IIIg. Age at onset subdivided in age bands of 10 years provides very relevant information since the risk for chronic complications increases with diabetes duration (51).

This indicator is relevant, however, certain considerations should be taken into account. Diagnosis for type 1 diabetes is straightforward. The diagnosis of type 2 diabetes is not always so simple and may be influenced by national policies (whether or not trying aggressively to identify the population with type 2 and/or impaired glucose tolerance).

As stated previously, type 2 diabetes may be detected only at the onset of complications (21% have some retinopathy at diagnosis). With the expectation that diagnostic approaches may be harmonised in near future, the indicator age at onset is included. At this time point the

first time any health care provider has mentioned the diagnosis diabetes is considered as age at onset.

Data source: DiabCare System data collection is proposed as source for this group of indicators. It offers the possibility to include both types, process and outcome indicators. Feed back of the information is possible towards health care provider and person with diabetes. Benchmarking is possible. All EU countries signed the S Vincent declaration, which has led to this data collection system (52.)
Core information includes the indicators of this section and is already available locally in most countries. Information can be obtained annually from both primary and secondary care.
Further harmonisation on national and international level is necessary before these indicators can be considered to be representative and thus allow international comparison.
The use of national /international structures to analyse core data has been started in several EU Countries (Portugal, Scotland, the Netherlands, Germany, and Denmark for paediatric care) (53). In Germany, the DPV group analyses information of more than 100 paediatric diabetes units through computer communication, allowing Centre Comparison and Quality Control, in an ongoing way. Continuously more units adhere to this central on individual initiative started data collection system (54-55).
Anonymity can be (and should) provided through the set-up of data transmission to the central institution.
Validation of completeness of the target population can be checked by point prevalence.
Once again, coverage in most countries is insufficient so far, but this should and must be improved in the near future.

Sentinel Practice Surveillance networks can provide some of the indicators. A bias is created by the fact that the specialists, thus providing an underestimation of the real situation, could see persons with complications more frequently.
Data collection through the unique national number and reimbursement structures, linking diabetes (identified through installed treatment) to laboratory analysis (HbA1c, lipid profile or microalbuminuria) and ophthalmologic examination can provide some indicators. No information on outcome indicators, blood pressure, height and weight or smoking habits are available and the 'diet only' population is excluded.

IV.   EPIDEMIOLOGY OF COMPLICATIONS

Retinopathy
For eye complications four indicators have been identified. Retinopathy can be subdivided in different stages of severity. Background retinopathy is characterised by mild non-proliferate abnormalities and increased vascular permeability. Gradually it evolves towards proliferate retinopathy. This form is characterised by the growth of new blood vessels on the retina and the posterior surface of the vitreous.
After 20 years of diabetes almost all persons with type 1 and > 60% of the persons with type 2 diabetes have to some degree diabetic retinopathy. (56-57)
Early diagnosis followed by an optimalisation of metabolic control can stop progression and in some situations prevent blindness. (Intensive insulin treatment and improved metabolic control (- 1% of HbA1c) was followed in UKPDS by 35 % less micro vascular complications (retinopathy, nephropathy, neuropathy). This necessitates a regular evaluation in all persons with diabetes.
If initial signs of retinopathy are found on clinical examination, besides a near normalization of metabolic control, laser coagulation may prevent ongoing visual loss.

IVa. The percentage of persons with diabetes with **fundus inspection** within the last 12 months is a process indicator, providing information on the frequency of eye control.
The percentage of persons with diabetes and a **fundus inspection which reveals proliferate retinopathy** is the outcome indicator.
The early diagnosis of retinopathy (so called background retinopathy) together with improved glycaemic control can stop progression of diabetes retinopathy. This confirms the necessity of regular control.
Once yearly fundus inspection is advised for persons with diabetes, who are 10 years of age or older, and/or persons of all ages with type 2 diabetes.
Data source: DiabCare System data collection is advised for this indicator. Validation of the process and outcome indicator can be obtained through unique national number/ linked to reimbursement system.

IVb. Laser therapy within three months after the diagnosis of proliferate retinopathy is the third indicator for monitoring diabetic eye complication.

This indicator has been included as it provides information on the therapeutic action following the diagnosis of proliferate retinopathy. The intervention may have a major impact on the visual acuity of the person with diabetes and provides relevant information on the quality of care.

Data source: DiabCare System data collection is advised for this indicator. Validation of the process and outcome indicator can be obtained through unique national number/ linked to reimbursement system.

IVc. The main outcome indicator for retinopathy is the annual incidence of end-stage retinopathy per 100.000 general population. Blindness due to diabetes is the core indicator of micro vascular pathology in the eyes. Definition of blindness in the different countries varies. Most reports use the legal definition of blindness for a certain country.

In many countries these definitions have been defined in a law due to the social and financial implications. In different EU/EFTA countries, registries of blindness have existed or still exist, using the national definition.

For monitoring diabetes, one of the most important indicators is the annual incidence of blindness due to end stage retinopathy in persons with diabetes mellitus. However, so far these data are unavailable in most EU countries. If a registry is available, it does not always include information on the presence of diabetes as possible causal affection. The importance of reliable information on this extremely important outcome indicator, a major complication of diabetes, imposes the (re) introduction of national registries for blindness with supplementary information on the cause.

Data collection should be performed through national registries of blindness, offering the incidence of end stage diabetic retinopathy as cause of blindness.

 DiabCare System data Collection can be used as secondary source as well as data obtained through SPSN

Nephropathy represents the second major micro vascular complication in persons with diabetes mellitus. Again delay and/or prevention of progressive nephropathy is possible with intensive treatment and

normal blood pressure. If no action is taken micro vascular lesions in the kidneys will lead to renal insufficiency. First signals are the detection of microalbuminuria, followed by an increase in creatinine levels. (58). Progression ultimately will lead to renal failure necessitating renal replacement therapy. Four indicators are proposed to monitor nephropathy, serum creatinine measurement (process and outcome indicator), incidence and prevalence of dialysis and transplantation.

IVd. Serum creatinine

Process indicator is the percentage of persons with diabetes with serum creatinine measurement in the last 12 months.

Outcome indicator is the percentage of persons with diabetes and a serum creatinine level ≥ 400 µmol/l. According to the WHO guidelines an increase of serum creatinine ≥ 400 µmol/l is considered as end stage renal failure and dialysis is imminent.

Data source: DiabCare system data collection previously described in more details, provides the information on these indicators. SPSN can provide interesting results but again with the same caveats as mentioned previously.

IVe. Incidence of dialysis and/or transplantation (renal replacement therapy) in patients with diabetes, (rate per million general population)

This indicator is available in most countries through national or international registries.

Dialysis and/or transplantation have been combined in one indicator " Renal replacement therapy". Separating these two therapies would provide more information on attitudes and availability of the specific therapy than of the real situation. Access to dialysis and transplantation may vary over the different countries. Since most registries include both renal replacement therapies, this is proposed as outcome indicator for end stage renal failure.

Data source: (inter) national registries

Validation of the registry data can be obtained through HDR and/or reimbursement structures information (dialysis and transplantation are both coded).

DiabCare System data collection can provide information on this item, however with the denominator chosen, national registries with information on diabetes seem best.

IVf. Prevalence (Stock) of dialysis and/or transplantation (renal replacement therapy) in patients with diabetes (rate per million general population).

This indicator is in most countries available through national or international registries.

Data source: (inter) national registries

Validation of the registry data can be obtained through HDR and/or reimbursement structures information (dialysis and transplantation are both coded).

DiabCare System data collection can provide information on this item, however with the denominator chosen, national registries with information on diabetes seem best.

Vascular disease

Peripheral vascular disease, in addition to peripheral neuropathy and duration of diabetes over 10 years increases the risk for gangrene, foot ulcers and amputation. This creates a major burden, emotional and financial, and a disability for the person with diabetes.

Myocardial infarction and stroke are increased in patients with diabetes mellitus as documented in many reports. Normalisation of metabolic control and lipid metabolism can reverse this increase, offering again the possibility to intervene in the ongoing destructive process.

IVg. Amputation

Annual incidence of non-traumatic (medical) amputations, above the ankle in persons with diabetes per 100.000 general population is the indicator for peripheral vascular pathology.

Data source for this indicator is the HDR diagnosis, surgical acts. In the majority of cases non-traumatic medical amputation above the ankle is caused by diabetes mellitus. However, diabetes may be underreported as second diagnosis, as shown in an UK investigation. Validation of the data should be provided by DiabCare System data collection.

Ivh. Stroke

Annual incidence of stroke in patients with diabetes per 100.000 general populations is the second indicator monitoring vascular complications in persons with diabetes.

The recommended definition of **stroke,** used by WHO, is a focal (or at time global) neurological impairment of sudden onset and lasting more than 24 hrs (or leading to death) and of presumed vascular origin (any permanent neurological brain damage, induced by vascular incidents). For this report the WHO definition of stroke is used.
Data source for this indicator is the HDR.
Risk of this data source is underestimation of diabetes on HDR. Further, depending on the health care system, patients may not always be referred to a hospital. If the stroke is severe, death may follow. Data on those patients may be lacking as well. Linkage procedures between mortality and the HDR are automatically performed through the "personal identification number" (ID) in Finland, Norway and Sweden, and through the name, date of birth and place of residence in Germany and Italy. This number, however, is expected to be relatively small. DiabCare System data collection questionnaire information may provide validation on HDR data.

IVi. Myocardial infarction

Annual Incidence of myocardial infarction in patients with diabetes per 100.000 general populations is the third indicator for vascular disease. Definition of myocardial infarction is the one used by the hospital coding registers. Recently new guidelines have been issued by the Joint European Society of Cardiology /American Cardiology committee 2000 236. They include biomarkers (cardiac troponin) for the diagnosis of MI as well as ECG changes. When these criteria will be implemented, an increase in incidence of MI in general may be observed since the new criteria are more sensitive and detect MI at an earlier stage. This may differ again from one country to another, depending on health care system.
Mortality linked with MI remains a potential risk for underestimation of MI in persons with diabetes.
Improvement and harmonisation of hospital data will influence the outcome of this indicator.
Data Source for all vascular indicators is the HDR.

IVj. Mortality.

Indicator for mortality is Annual death rate per 100.000 populations in the general population from all causes, adjusted for standard European population and the Annual death rate per 100.000 populations in patients, who have as primary or secondary cause of death, diabetes mellitus, adjusted for standard European population.

For obvious reasons, the death rate should be age (in 5-10year bands) and gender linked.

The major outcome indicator for diabetes complications is death.

Data sources are the national registries.

National institutes in most EU /EFTA Countries have data available on mortality. Diabetes as primary or secondary cause may be underreported. Information on the death certificates may vary from country to country, and variation in the filling out of these forms exists. It remains, however, one of the key indicators of diabetes outcome and needs to be included.

Persons with Diabetes anywhere on the death certificate will be included.

V.   Future Indicators

a + b.   Not yet included in this project are the acute complications, such as incidence of severe hypoglycaemic events (a.) and diabetic ketoacidosis. (b.) Although their impact on quality of life and their financial impact (lost working days, hospitalisations etc) are considerable, the group chose to concentrate on the core and second indicators. The definition, as well as the documentation of these complications still varies considerably.
It may need no further comment, that in future indicators for acute metabolic complications need to be integrated in the list.

c.   Quality of life is actually being evaluated by a large number of different questionnaires adapted for different age groups. (HAPPI, Eli LiLLy, Pfizer, WHO) At this stage, no final tool is available to test and compare the situation in the different member states.
Nor is yet a comparison available within the background population. It definitely needs further research to include this important indicator to monitor quality of life in persons with diabetes.

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Chapter 2

Pilot Study EUDIP - 2001

I	Risk factors for type 2 diabetes	(table 1)
II	Epidemiology of diabetes	(table 2-3)
III	Risk factors for diabetes complications	(table 4-9)
IV	Epidemiology of diabetes complications	(table 9-17)

Introduction

A pilot study was performed within the participating countries to evaluate the feasibility to obtain data on the proposed indicators and to investigate the quality and comparability of the existing databases in the different countries. Due to an enormous variability in data collection and important lack of data in the different EU countries, most data are summarised anonymously to prevent too hasty conclusions linked to specific data. Data are given to provide insight in the actual situation, using the information of submitted questionnaires (annex 1)

I   Risk factor for type 2 diabetes

Table 1

Risk factor for Type 2 diabetes							
BMI -% of general population >30 kg/m^2							
Source	NR/R	Population	Year	male	female	male	female
						1996- Eurobarometer	
HIS	R	n= 59 349	1999	7	7	5,9	6
HES	NR	n=21356	94-97	14	13	6,5	8,3
HES	R	n=6772, m:44%	2001	21,2	23,5	8,6	8,2
HES	R	n=7124	1998	12,1	10,9	5,4	3,8
HIS	R	n=140.000	5 yrs	9,1	9,1	4,3	5,4
HIS	R	n=300 (eurobarometer)	1996	8,5	7,1	8,5	7,1
HES	R	n=9877	1999	8,6	10,2	2,9	6,8
HIS	R	n=38688, m 46,9%	98-99	11,4	14	7,9	9,4
HES	R	n=14330, m 46%	1998	17,3	21,2	8,1	10,1

R   : representative

NR: not representative

Table 1 shows the difference in BMI results, obtained in different EU countries, using different data sources. National HES/HIS data collections are compared with Euro barometer data (HIS) in 1996. The difference between the data obtained through these sources seems linked - at least partly - to the data collection.

The variation between HIS and HES is not systematic and varies per country (2:1→3:1).
Underestimation of obesity is observed when data are collected through self-report. However, to what extent the number is underestimated, varies per country. Self-report will lead to an underestimation of the risk factor. Although HES are more time and money consuming, the difference in outcome clearly shows the importance of an examination to obtain comparable and reliable data.

II Epidemiology of diabetes

Table 2
Epidemiology of diabetes

Annual incidence of type 1 diabetes by age 0-14 yrs per 100.000 population 0-14yrs

Country Source	Standardised Incidence	year RESULTS
	EURODIAB 1989-1999	
	total *	
AU national register, ongoing,	1998 9,56 9,5	
B national register, ongoing,R	1989-1995 11 11,8	

DK
Na

na
16,8

F
national register, R

2000
49,1
43,9

FR
National register , stopped

Na
8,3*

G
national register, stopped,
 n= 1944

1987/1997
12,50
12-13,2

GR
regional registry (Attica) NR

9,70
6,2-9,7

IC
Na

Na
13,9

IRL
Na

Na
na

IT
regional registries,

every 5yrs
6 –10
8,7-12,3-37,8

L
national register, ongoing

1998/2000

11,8
11,9

NL
regional register, stopped (?)

Na
13,0*

N
national register, ongoing

1999
21,50
20,8

P
Na

Na
6,9-16,0

Sp
Na

Na
12,8

Sw
incidence study

Na
25,7

UK
regional, R, not ongoing

1995
25,90
17,1-19,3- 22,3

: not available
*1989-1994

Incidence of type 1 diabetes has been extensively studied through the
EURODIAB project, 1989-1994 (chapter 1, ref 3-8).

Through Eurodiab, registries all over Europe have been created to monitor with comparable methodology (information through 2 independent sources) the incidence of type 1 diabetes. Different regions within the larger EU countries show different incidences, with the most important differences in Italy (Sardinia compared to the mainland.)

The data obtained through the actual project are compared with the previously published data. In some countries the same source (registry) has been used, whereas in other countries the data from the EURODIAB project have been submitted since the registry has been stopped.

Variation in incidence, stable or increase, is observed in the remaining countries. Since environmental risk factors probably play a role, a continuous monitoring of the incidence of type 1 diabetes mellitus remains important. Through a national registry or a regional registry, provided its representativity, incidence of type 1 diabetes in children between 0-14 years should be monitored.

Table 3

Epidemiology of diabetes					
Prevalence of type 1 and type 2 diabetes/1000 population					
	SOURCE	year	RESULT	Male	female
HIS	R,n= 59.349 , M:48.3 %	1999		13,4	15,7
HES	NR, n	1998	38		
HES	N= 7080,R	2001		39	37
HES	R,. n=7099,	1998		47	56
HIS	N= 19 570	annually	27-37		
R S	R, n=	2000		29,4	27
SPSN	R,n=123 347	1999		24,7	26,4
HES	NR, n=126.000	1995-1997	25		
HIS	R, n=2580,m 41.8%	1998-1999	*5,3--20--31,7		
HIS	R, age 16+, M:46,8 %	1998		33	25
HES	R	2000	25,1		

R   : representative

NR: not representative

*3 different sources being used in the same country: HIS-SPSN-UNN

In table 3 prevalence of type 2 diabetes is estimated through different data sources in the EU/EFTA Countries. HES provide the most complete and reliable data, including persons treated with medication (either insulin or oral hypoglycemic medication) and with diet/exercise only. In 5 countries, data have been obtained through HES, whereas HIS has been used in 3 countries. The difference observed in the outcome does not seem to reflect the real difference between countries. In one country, three different sources have been used, clearly demonstrating the effect of HIS versus SPSN and unique number data.

Reimbursement Structures (RS) provide reliable data in those countries, where a national (or almost nationwide distributed) social security system exists. They always exclude the group not treated by medication. Treatment policy may vary per country, resulting in different outcome with respect to prevalence.

Several countries have a large number of possible insurance companies, representing a second disadvantage of this data source as standard one.
Once again, it accentuates the importance to identify one data source in EU /EFTA countries, if comparisons are to be made.
HES will be providing the most complete and best comparable data to monitor diabetes prevalence.
If not available/possible, social security will offer reliable data provided one takes into account the absence of the non treated group (1) and treatment policy differences between countries (2).

III Risk factors for diabetes complications

Table 4

Risk factors for complications (people with diabetes)	
PROCESS INDICATOR HbA1c:	
Percent tested in last 12 months	
OUTCOME INDICATOR HbA1c:	
percent >7.5% in last 12 months	

R	SOURCE	Year	process	outcome
			results	results
nr	DiabCare n= 4344	1999	97.2%	64.1%
nr	Diabcare n=7416	2001	97,40%	>7%: 69,8%
nr	Regional, n=2100	2000	83%	61,6%
nr	Diabcare, n= 8049, m:49%,	1999	92,73%	51.04%
nr	DiabCare, sec care, n=7000	1999	70%	60%
nr	DiabCare, sec care, n=19 570	1999	Na	55%
r*	primary care n=1318	1999	99.7%	44.4%
nr	primary care, n=1654 m:51%	1994-1995	84%	54%
nr	DiabCare, primary care n=14 580	1999	51,2%	40,4%
nr	DiabCare , n=154 170, m:54.3%	1998	66.9%	**HbA1c>8%:**45.4%
nr	DiabCare, n=8212	2000	90.9%	**HbA1c>7%:**71,7%

R : representative

Nr: not representative

Table 5

Risk factors for complications in persons with diabetes mellitus					
PROCESS INDICATOR					
Percent with lipid profile in last 12 months					
OUTCOME INDICATORS	Percent with total cholesterol >5mmol/l in last 12 months				
	Percent with LDL >2.6 mmol/l (*> 3 mmol/l) in last 12 months				
	Percent with HDL<1.15 mmol/l (*<1.0 mmol/l) in last 12 months				
	Percent with triglycerides >2.3 mmol/l in last 12 months				

R*	source	year	Process result	Outcome CHOL	LDL	HDL	TG
nr	DiabCare, n= 4344	1999	97%	61.1%	78%	36.4%	21,4%
nr	Diabcare, n=7238 (>18yrs)	2001	85,9*%	88%	52,7%	45,4%	19,9%
nr	Regional, n=2100	2000	64%	60%	*57%	*29%	36,5%
nr	Diabcare, n= 8049, m:49%,	1999	80%	72%	Na	47.3%	36,38%
nr	DiabCare, sec care, n=7000	1999	100%	80%	80%	60%	60%
nr	DiabCare, sec care, n=19 570	1999	Na	69%	72%	41%	40%
r*	primary care n=1318	1999	99.4%	73.1%	84%	40%	23,7%
nr	primary care, n=1654 m:51%	1994-1995	51%	79.6%	Na	46.1%	41,6%
nr	DiabCare, primary care n=14 580	1999	59,8%	Na	Na	na	na
nr	Diabcare, n=154 170, m:54.3%	1998	41.2%	60,4%	Na	na	na
nr	DiabCare, n=8212	2000	70.7%	Na	Na	na	na
		2001				41%	

* smaller numbers tested for LDL (44,9%), HDL (82,8%), and TG (48,1%)

Table 6

Risk factors for complications					
(people with diabetes)					
Microalbuminuria:					
PROCESS INDICATOR :percent with µ-albuminuria analysis in the last 12m					
OUTCOME INDICATOR: percent with positiveµ-albuminuria in the last 12 m					
	Source	year	Process%	Outcome%	
nr	DiabCare, n= 4344	1999	68	14.9	
nr	Diabcare, n=7238 (>18yrs)	2001	65,3	27	
nr	Regional, n=2100	2000	57	na	
nr	Diabcare, n= 8049, m:49%,	1999	69,4	28.36	
nr	DiabCare, sec care, n=7000	1999	20	5	
nr	DiabCare, sec care, n=19 570	1999	Na	22	
r*	primary care n=1318	1999	99,4	25	
nr	primary care, n=1654 m:51%	95-97	25	23,9	
nr	DiabCare, primary care n=14 580	1999	3	na	
nr	DiabCare n=154 170, m:54.3%	1998	28,8	17,4	
nr	DiabCare, n=8212	00-01	28.8	na	

Table 7

Risk factors for complications			
(people with diabetes)			
Blood pressure:			
PROCESS INDICATOR Percent tested in last 12 months			
OUTCOME INDICATOR Percent with BP>140/90 in last 12 months			
Source	year	Process (%)	Outcome(%)
DiabCare, n= 4344	1999	98.5	42.5
Diabcare, n=7238 (>18yrs)	2001	94,4	54,8
Regional, n=2100	2000	93	55
Diabcare, n= 8049, m:49%,	1999	96.76	syst 61.7%, diast 31.5%
DiabCare, sec care, n=7000	1999	100	50
DiabCare, sec care, n=19 570	1999	na	22 (syst 70%, diast 25 %)
Primary care n=1318	1999	99.6	61.4 (syst 56.3%,diast 29.3%)
HES	95-97	86	72.2 (70.5% systolic, 31.6% diastolic)
DiabCare, primary care n=14 580	1999	62,7	72,8
DiabCare; n=154 170, m: 54.3%	1998	64.6	24.4
n=6712	00-01	74.9	syst 42.9% diast 8%

Table 8

			Year	results
Risk factors for complications (people with diabetes)				
Percent smoking				
	source		Year	results
nr	DiabCare, n= 4344		1999	18.8%
nr	Diabcare, n=7238 (>18yrs)		1999	19%
nr	Regional, n=2100		2000	19
nr	Diabcare, n= 8049, m:49%,		1999	13.67%
nr	DiabCare, sec care, n=19 570		1999	13%
nr	HES, n=1822, > 20yrs		95-97	16.8%
nr	DiabCare, primary care n=14 580		1999	0,50%
nr	DiabCare; n=154 170, m:54.3%		1998	12.,8%
nr	N=6712		00-01	20,5.%

Table 9

		Year	>25kg/m²	>30kg/m²
Risk factors for complications (people with diabetes)				
Percentage with BMI > 25kg/m², >30kg/m²				
	Source	Year	>25kg/m²	>30kg/m²
nr	NR, n= 4156	1999	65.7%	41,5%
nr	Diabcare, n=5648	2001	71,5%	35,9%
nr	Regional , n=2100	2000	na	30
nr	Diabcare n= 8049, m:49%	1999	75.07%	38,64%
nr	sec care , n=7000	1999	60%	40%
nr	sec care, n= 19570	1999	82%	38%
r*	prim care n=1318	1999	83.3%	40,1%
nr	HES n=1972	95-97	76.1%	35,7%
nr	HIS ,n=38.688	1999	49,5%	12,8%
nr	n=8212	00-01	77.8%	40%

In the previous tables, process and outcome indicator results are given. No comparable data sources are yet available. The summarised results are obtained through sources differing in size, place and representativity for the given country. The data are given anonymously in order to prevent comparisons between sources that have to improve in comparability. The outcome results (% of persons with specific risk factors for complications) are based on the process indicators, e.g. the percentage mentioned in the process indicator is considered as 100%. No information is available on the patients NOT seen in the previous 12 months. Although not yet representative, DiabCare data collection seems an interesting source for future, combining

information about the health care provided
information for the health care provider
information for the patient

Although the results can not be considered as robust indicators and are not yet ready to be used for international comparison at large scale, they become so within next decade.
Harmonisation between core data collection in EU/EFTA countries should be stimulated as well as their introduction in those countries, where no data collection exists. Future projects should evaluate the possibility to collect and monitor through a central structure (e.g. EUROSTAT) these indicators. Finally for the indicator evaluated the influence of duration of diabetes (age at diagnosis by 10 year age bands) only three countries were able to contribute data, whereas none of the three was yet considered to representative. Therefore, these results have been omitted from this chapter.

IV EPIDEMIOLOGY OF COMPLICATIONS

Table 10

Epidemiology of complications			
Retinopathy:			
PROCESS INDICATOR Percent with fundus inspection in last 12 m.			
OUTCOME INDICATOR Percent with prolif. Retinopathy in last 12 m.			
OUTCOME INDICATOR Percent with laser treatment<3m after diagnosis			
	Source	process %	Outcome %	laser %
nr	DiabCare n= 4338	61.2%	3,4	na
nr	Diabcare, n=7416	99,9	0.04	na
nr	Regional, n=2100	38%	na	na
nr	Diabcare n= 8049, m:49%,	52.62%	4,75	na
nr	Sec care , n=7000	90%	30	5
r*	Primary care n=1318	78.7%		na
nr	DiabCare primary care	53%	na	na
nr	DiabCare primary care	29	0,26	53,5
nr	DiabCare n=154 170	61.1%	11,3	na
nr	n=8212	62.6%		na

Only in one EU/EFTA country, data were available on the number of persons with blindness due to diabetic retinopathy compared with the incidence of blindness in the general population. In some countries registries exists, however not including the information on the cause. In othere countries (3), data was available through DiabCare sources and thus using the diabetic population as denominator. This very important outcome indicator cannot yet be monitored in many countries and if some data exist their difference in source prohibits any

comparison, in contrary to other outcome indicators. Preferably through the national registries on blindness, information should be made available on the number of persons developing blindness due to diabetic retinopathy, compared with the number of people developing blindness in the general population. Information on the number of persons with diabetes having had eye check information was forwarded through DiabCare and through RS. The representativity of these data is not yet allowing any international level. As mentioned previously, this should be possible over the next decade.

Table 11

Epidemiology of complications				
Nephropathy:				
PROCESS INDICATOR Percent with serum creatinine tested in last 12 m				
OUTCOME INDICATOR Percent with ESRF - serum creatinine>400 µmol/l in last 12m				
nr	DiabCare n= 4344	1999	95.8%	0,8
nr	Diabcare n= 8049, m:49%,	1999	84.73%	0,57
nr	Prim care : n: 1939,	1999	99.4%	0.01
r	HES	95-97	na	0,1
nr	N=10127	00-01	na	0,05

Table 12

Epidemiology of complications			
Nephropathy:			
Annual incidence of dialysis in patients with diabetes/1000.000 general population			
Annual incidence of transplantation in patients with diabetes/1000.000 general population			
Source	Year	dialysis	transplantation
nat dialysis/transplant register	1999	41	6,8
national register,	1999	30,6	11,2
renal register	1999	19,2	Na
national registry	1998	22	Na
national register	1999	13,7	0
national register	2000	17,8*	17,8*
renal register	1999	14,5	5,4

Table 13

Epidemiology of complications	

Nephropathy:

Prevalence (stock) of dialysis in patients with diabetes /1000 000 general population
Prevalence (stock) of transplantation in patients with diabetes/1000.000 general population

source	year	dialysis	transplants
national dialysis/transplantation register	1999	86,4	34
national register,	1999	67,8	76,6
nat dialysis& transplant register	1999	173,5	na
national registry	1999	127	na
national register	1999	34,2	14,5
renal register	1999	28,1	17,5

Only in 5 countries, information is available on serum creatinine levels, despite its recognised role as an important indicator of imminent renal failure. Data collection through DiabCare should provide better information on this indicator over the next decade.

National and international registries collect information on dialysis and transplantation. By tradition expressed in x/1000.000, many countries have or will within shortly dispose of information on the dialysis/transplantation in diabetic persons. Using the information of Reimbursement Structures for checking possible missing data could perform a control of the data. (HDR for dialysis/transplantation and diabetes), thus providing reliable information. With respect to the differences in dialysis and transplantation, observed between the countries, reliable data on the incidence of ESRF as well as information on the local structure should be included. In some countries accessibility to dialysis or transplantation may not be comparable, thus explaining part of the different outcome.

Table 14

Epidemiology of complications
Vascular disease:

Annual incidence of amputations above the ankle in patients with diabetes/100.000 general population		
HDR	1999	6,75
national register, Reimbursement Structure	1999	29
HDR ICD 10,	2000	458
Diabcare n= 8049, m:49%	1999	360.3*
Sec care, NR, n=7000:	1999	100*
ICD 9, amputees, hospital discharge., n= 19570	1999	4,9
HDR	1999	6,3
HDR	00-01	4,6
LOWER LIMB amputation	2000	29,6

Table 15

Epidemiology of complications
Vascular disease:

Annual incidence of stroke in patients with diabetes/100.000 general population		
Source	year	result
hospital discharge, ICD	1999	64,2
Diabcare, n= 8049, m:49%	1999	193
Sec care n=19570	2000	13
national register	1999	12,9
HDR	1999	60,95
HDR	2000/2001	21.68
Prim Care n=10127	2000	296,2

Table 16

Epidemiology of complications
Vascular disease:

Annual incidence of myocardial infarction in Patients with diabetes/100.000 general population		
HDR	1999	36,05
DiabCare n= 8049, m:49%,	1999	279
Secondary care n=19570	2000	38
national register	1999	12,9
HDR	1999	16,7
HDR	00-01	51,24
Prim care , n=10127	2000	345,6

Table 17

Epidemiology of complications
Mortality:

Source	Year	diabetes: primary/sec cause			mortality from all causes		
		total	male	female	total	male	female
national register*	1999	12..3%	12.9%	11.6	707,1		
national register*	1999	15..7	11,8	19,6	1006		
national register*	1998	101			965		
national register*	1999	25..5			1031		
regional register *	2000		27,1	25,1		1075,3	631,4
national statistical dept.*	2001	12,2	11,5	13,4	867,4	859	875,4
national statistical dept.	1999*	21			888,5		
national statistical dept	1999*				1011,1		
national statistical dept.*	1999	25	26,4	23,9	829	1066,6	643
National statistical dept.	98-00	30,8	39	24,7	699,3	864	575

Above the ankle amputation for non-traumatically cause is mainly performed due to diabetes. The indicator is collected in different ways with in the different countries different denominators. The best available indicator is the incidence of above the ankle amputations in persons with diabetes per 100.000 general population, using HDR as source.

One has to be aware of the underestimation of diabetes on HDR. Through a different HMP, an evaluation of the recording on HDR is performed, improving (inter)national comparisons, based on this data collection.

In some countries DiabCare is proposed as source for amputations, using as persons with diabetes as denominator. The collection through HDR seems more reliable for this indicator and, taken account of possible influences of the quality of HDR, is the indicator source to monitor vascular complications. Stroke incidence over EU is obtained through diverse sources, causing large variations in outcome. Again, nominator and denominator are different, stressing the importance of harmonisation. In most countries, persons with a stroke will be hospitalised. The best source is data collection through HDR. Information on diabetes may be underreported in hospital records, thus leading to an underestimation of the incidence. With correct reporting of diabetes in the HDR, this source seems the best.

As second source DiabCare could be used, however creating possible confusing again, due to a different denominator (persons with diabetes). Underestimating stroke in this population can be caused by a change of consultation pattern by those who have had a stroke (more specialised neurological secondary care) and thus including the persons with a stroke in the group that has not consulted. So far, this is an important bias in the DiabCare data collection. When nationwide representative annual data

collection takes place, it may provide a second reliable source for monitoring stroke in persons with diabetes.

For myocardial infarction, information is again obtained through Hospital Discharge Records. The same comments on the risk of underestimation as mentioned above apply to this category as well. Most people will be hospitalised and just underreporting of diabetes should be improved.

Mortality
Diabetes as primary or secondary cause of death is often underreported. No standardised age group data, linking mortality to diabetes as primary and/or secondary cause are available in most countries. Being the final outcome indicator, this indicator needs to be made available in all EU/EFTA countries.

CONCLUSION

The results of this pilot study on indicators, monitoring
          Risk factors for type 2 diabetes   (table 1)

Epidemiology of diabetes-   (table 2-3)
Risk factors for diabetes complications   (table 4-9)
Epidemiology of diabetes complications   (table 9-17)

clearly show the strong and weak points in the actual situation in EU/EFTA countries.

For the different indicators monitoring diabetes mellitus a large number of data sources are available and used in EU/EFTA countries, rendering interpretation of outcome very difficult.

As main conclusion, Health Examination Surveys and Pathology specific ONGOING registries provide data already in most EU/EFTA countries, in a continuous, reliable and comparable way.
Within the next 5 years these, mainly core, indicators should be available in all EU/EFTA countries and allow international comparison.

For some indicators, a surprising lack of data or of comparable data has been detected, needing national action and re-evaluation over the next years. No data could be obtained - for example - on the number of persons with diabetic retinopathy in the total population of blind persons.

Interesting information on risk factors for diabetes complications in the diabetic population has been obtained through DiabCare collection. No international comparison is possible yet through these sources, due to major differences in representativity and completeness. It has not been developed to perform epidemiological studies, but to improve local clinical care.
However, if the methodology of data collection can be standardised and completeness of these sources can be improved, they may be an interesting source of indicators, monitoring continuously risk factors of diabetes complications in an appropriate way, offering as well direct feed back to health care providers.
For future developments, flexibility with respect to cut off limits and possible new international diagnostic definitions (myocardial infarction, stroke etc) must be present.
Early detection of risk factors and complications will -in long term - improve outcome and reduce human burden and financial costs enormously. Taking the actual situation into account, it seems extremely important to improve comparability between data collection in the EU/EFTA countries, and use the existing bases to start. Standardisation of laboratory techniques and/or modifications of cut off levels need continuous follow up.

In summary, all EU/EFTA countries should create and/or improve the collection of the core data set over the next years.

Further projects should aim at improvement of comparability of the data sources, including core and secondary indicators.

Chapter 3

a. Final Shortlist of Indicators

PROPOSED INDICATORS FOR DIABETES MELLITUS

EUDIP SHORTLIST

Core indicators   Second indicators

INDICATORS	DATA SOURCE
RISK FACTORS FOR TYPE 2 IABETES	
Obesity **BMI - % of general population ≥30 kg/m^2**	HES (nat-reg)/HIS
EPIDEMIOLOGY OF DIABETES	
Annual incidence of Type 1 diabetes by age/100,000 population 0-14 yrs,	Registry/UNN/RS
Prevalence of diabetes mellitus /1000 population	HES / HIS/ SPSN/UNN/Survey
Prevalence of persons with impaired glucose tolerance and or, diet only	HES/SPSN
RISK FACTORS FOR COMPLICATIONS (IN PEOPLE WITH DIABETES)	
HbA1c: Percent tested in last 12 months Percent >7.5% in last 12 months	DiabCare /SPSN/*UNN/RS
Lipids: Percent with lipid profile in last 12 months* Percent of those tested with total cholesterol >5 mmol/l Percent with LDL>2.6 mmol/l (>3 mmol/l) Percent with HDL <1.15 mmol/l (<1.0mmol/l Percent with triglycerides >2.3 mmol/l (>2.0mmol/l)	DiabCare/SPSN *UNN/RS
Microalbuminuria: Percent tested in last 12 m* Percent with microalbuminuria in last 12 m	DiabCare/SPSN/*UNN/ RS
Blood pressure: Percent tested in last 12 m Percent with BP >140/90 in last 12 m	DiabCare/SPSN
Percent of the persons with diabetes who are smoking	DiabCare/SPSN
Percent with BMI ≥ 25 kg/m2, ≥ 30 kg/m2	DiabCare/SPSN
Age at diagnosis by 10 year age bands	DiabCare/SPSN
EPIDEMIOLOGY OF COMPLICATIONS	
Retinopathy: Percent with fundus inspection in last 12m	UNN/RS/DiabCare

Percent with proliferate retinopathy in last 12m	DiabCare/SPSN
Percent who received laser treatment <3 months after diagnosis	UNN/RS
Annual incidence of blindness due to diabetic retinopathy/total annual incidence of blindness	National Registry
Nephropathy:	
Percent with serum creatininee tested in last 12 m*	DiabCare/Sentinel *UNN/RS
Percent with ESRF - serum creatininee $\geq$ 400 μmol/l (WHO definition) - in last 12 months	
Annual incidence of dialysis and or transplantation (renal replacement therapy in patients with diabetes/1,000,000 general population	National Registry UNN/RS
Prevalence (stock) of dialysis/ transplantation (renal replacement therapy) in patients with diabetes/1,000,000 general population	National registry/UNN/RS
Mortality	
Annual death rate in patients who have as primary or any cause of death diabetes mellitus/100,000 general population, adjusted for European Standard Population	National registry
Annual death rate in the general population from all causes/100,000 general population, adjusted for European Standard Population	National registry

ICD9   : Diabetes mellitus   250
ICD 10 : Diabetes mellitus E10-14

Chapter 3
b. Detailed description of proposed indicators

This chapter summarises a detailed description of the chosen indicators and their possible data sources.

Obesity

Indicator: BMI $\geq$ 30 %

Definition: BMI is body mass index, expressed as the weight per squaremeter through self-report (Health Interview Survey) or through measurement (Health Examination Survey), with a preference for the second source.

Data sources: HES every 3-5 years, national or regional if regional, representativity should clearly be defined.
HIS, annually, this would monitor national trends.

Indicators characteristics:
relevance   yes
validity   yes
comparability HES   yes,
HIS   not certain
reproducibility and sensitivity   yes
feasibility   probably
population: gender and age group in 10 year groups: $\geq$ 25-64 years:

where possible <25 yrs, >64 yrs
$\rightarrow$whole population

Annual Incidence of type 1 diabetes mellitus,

Definition: number of children between 0-14 yrs, diagnosed yearly with type 1 diabetes mellitus in a specific region/country per 100.000 children between 0-14 yrs in the study region/country.

Data source: ongoing national registry and/or a registry in a representative region for a given country, with the capture/recapture data collection (2 independent data sources required, insurance or national number and

diabetes association, registry through diabetes centres, prescription of insulin.

Indicator characteristics:

relevance	yes
validity,	yes
comparability	yes
reproducibility and sensitivity	yes
feasibility	probably, since it has been available in most EU countries
population:	all children between 0-14 yrs. If a region is studied its representativity should be clearly stated
frequency:	ongoing

Prevalence of diabetes mellitus

Definition: point prevalence of diabetes mellitus is the number of persons at a given time in which diabetes mellitus has been diagnosed. Diagnosis of diabetes mellitus is based on the definition of WHO: classical clinical symptoms or fasting plasma glucose $\geq$ 126mg/dl, (7.0mmol/l) and/or postprandial 2hr $\geq$ 200mg/dl (11.1mmol/l).

Data source: Health Examination survey (HES-1)
                    Health Interview Survey   (HIS-2)
                    Representative sample of the national or regional population
                    Gender and Age per 5 –10yrs bands,
                            (1) every 3-5 yrs
                            (2) yearly

Health examination and Interview survey (1+2)
Questions :
1- Have you ever been told by your doctor that you have diabetes?
            1-Yes, 2-No, 3-uncertain
2- Are you currently taking insulin or pills to control your diabetes?
            1-Yes, 2-No, 3-uncertain
3- Are you currently following a diet to normalise your bloodsugar levels?
            1-Yes, 2-No, 3-uncertain
Blood glucose measurement according to description (HES)
HES(1) :Fasting plasma glucose and if $\geq$ 126mg/dl, propose OGTT

Validation source: Unique National number/reimbursement structure/drug sales

Disadvantage: no information on persons treated with a diet only will be obtained, nor any information on the population with IGT.

Sentinel Practice Surveillance Network (SPSN)

>Prevalence of IGT and type 2 diabetes in persons, seen over a defined time period in the sentinel practice surveillance network.

Disadvantage: although motivated, only primary care is involved It is not yet available in all EU countries. The representativity for a specific country should be carefully analysed.

Indicator Characteristics :

	HES	HIS	Nat Number	SPSN
relevance	yes	partly	partly	yes
validity	yes	yes	yes	yes
comparability	yes	yes	not certain	maybe
reproducibility/ sensitivity	yes	yes	yes	maybe
feasibility	maybe	possible	no	possible

population	at least : 25-64 yrs
	preferable: inclusion of all ages
frequency	every 3-5 yrs

Risk factors for complications

Metabolic control

Indicator	glycosylated haemoglobin A1c
Process indicator	percentage of persons with diabetes with a HbA1c control within the last 12 months
Outcome indicator	Percentage of persons with diabetes with HbA1c control within the last 12 months and a value ≥ 7.5 %. HbA1c measurement should be validated with the golden standard DCCT value.

Data source*	Nationwide DiabCare system data collection questionnaire (1) (see example pg1-3: examples of sheets used for persons with diabetes, either by primary or by secondary care provider.) This sheet should be forwarded to an (inter) national structure for evaluation and feedback.
	A core list of information on the data sheet is obligatory, whereas depending on policy, new developments etc various items can be susceptible to modification. Assessment of completeness should be obtained by regular (every 3 years) estimation of the process indicator through a secondary source. Insurance/national number/survey within patient organisations should provide information on the number of persons with diabetes having had HbA1c control.
Validation	SPSN (2)
Disadvantage:	only primary care, whereas in more complicated situations secondary care might be more involved Unique national number (reimbursement structure) (3)
Disadvantage	Only process indicators.

Patient organisations (4)

	A survey by the patient organisation will provide again an assessment of the completeness of the primary source. Through a questionnaire, self-report information can be obtained.
Disadvantage	lack of direct feed back to the health care provider and the patient

Process indicators

indicator characteristics:	1	2	3	4
relevance	yes	yes	yes	yes
validity	yes	yes	yes	yes
comparability	in time	maybe	no	no
reproducibility/ sensitivity	in time	yes	yes	yes
feasibility	possible	may be	no	may be

Outcome indicators

indicator characteristics:	1	2	3	4
relevance	yes	yes	yes	yes
validity	yes	yes	na	na
comparability	in time	maybe	na	na
reproducibility/ sensitivity	in time	maybe	na	na
feasibility	possible	may be	no	no

Population   all persons with diabetes mellitus

Frequency   annually

Dyslipidemia

Indicator   lipid profile

Process indicator   percentage of persons with diabetes with a lipid profile (total cholesterol, LDL; HDL and triglycerides) measured within the last 12 months.

Outcome indicator   percentage of persons with diabetes with a lipid profile, measured within the last 12 months and the following results
total cholesterol >5 mmol/l
LDL >2.6 mmol/l
HDL <1.15 mmol/l
triglycerides >2.3 mmol/l

Data collection: see *
Population
Frequency

Microalbuminuria

Indicator   microalbuminuria

Process indicator   percentage of persons with diabetes with a control of microalbuminuria

Outcome indicator   percentage of persons with diabetes with a control of microalbuminuria and a positive result, defined as a 24hrs collection with microalb. >30mg/24h, a timed collection with a value > 20 µg/min or a spot collection with microalbuminuria >30 µg/mg creatinine

Data collection: see *
Population
    Frequency

Hypertension

Indicator   blood pressure

Definition   blood pressure measured with a standardised manometer, expressed in mm Hg
Process indicator   percentage of persons with diabetes and a blood pressure measurement with the last 12 months
Outcome indicator   percentage of persons with diabetes who had their blood-pressure taken and in whom systolic values ≥ 140 mm Hg and diastolic values ≥ 90 mmHg were detected. (WHO recommendations of cut off levels).

Data collection: see *
Population
Frequency

Tobacco use

Indicator   smoking
Definition   smoking is considered smoking of any kind of tobacco at the time of reporting (not including those who have been smoking and who have stopped)

Outcome indicator   the percentage of persons with diabetes who are actually smoking, including cigars, cigarettes and pipe.

Data collection: see*
Population

Frequency

Overweight/Obesity

Indicator   Overweight/BMI $\geq$ 25 kg/m^2
                     Obesity BMI $\geq$ 30 kg/m^2

Definition   Percentage of persons with diabetes mellitus and a
                     BMI $\geq$ 25 kg/m^2
                     BMI is Body Mass Index, expressed as the weight per
                     square meter
                     Percentage of persons with diabetes mellitus and a BMI
                     $\geq$ 30 kg/m^2

Data collection: see *
Population
Frequency

Diabetes duration

Indicator   age at onset of diabetes

                     The **age at onset** subdivided in age bands of 5 –10
                     years,
                     Age at onset is defined as the age at which the
                     diagnosis diabetes has been transmitted.
Data source: see*
Population*
Frequency*

Epidemiology of diabetes complications
Retinopathy

Process Indicator: Percentage of persons with diabetes mellitus with
                        fundus inspection in last 12 months
Outcome indicator: Percentage of persons with diabetes mellitus with
                        a fundus inspection in the last 12 m, who has
                        proliferate retinopathy

Proliferate Retinopathy is defined as the presence of the growth of new blood vessels on the retina and the posterior surface of the vitreous.

Data source: see*
Population*
Frequency*

Outcome indicator: Percentage of persons with diabetes mellitus who received laser treatment <3 months after diagnosis Of proliferate retinopathy

Data source : see*

Validation: reimbursement structure in some countries has a code for laser therapy. This, in combination with ICD Coding (9 or 10) for diabetes, will offer the possibility to validate the primary source

Population: all persons with diabetes mellitus

Frequency   annually

Outcome Indicator   Annual incidence of blindness due to diabetic retinopathy in persons with diabetes mellitus/annual incidence of blindness in the general population

Definitions (as used actually in the different Member States)

Central vision acuity in both eyes less than 0.6 of normal sight after correction (Belgium)

Visual acuity lower than or equal to 6/60(Denmark)

Visual acuity of 2 % or less of normal eyesight and other impairments of visual acuity of the same gravity (Germany)

Visual acuity inferior or equal to! /10 for each eye or nil at one eye and inferior or equal to 2/10 at the other (France)

Visual acuity less than 1/20 of normal eyesight in both eyes after correction (Greece)

Visual acuity less than 2/20 of normal eyesight in both eyes after correction (Ireland)

Visual acuity less than 1/10 of normal eyesight in both eyes after correction (Italy)
Visual acuity less than 1/10 of normal eyesight in both eyes after correction or visual field inferior to 10o (Luxemburg)
Visual acuity less than 1/10 of normal eyesight in both eyes after correction or visual field inferior to 20o (the Netherlands)
Visual acuity less than 0.05 (Portugal)
Visual acuity less than 1/10 of normal sight in both eyes after correction or visual field inferior to 10o (Spain)
Visual acuity of between 3/60 and 6/60 Snellen and a full field of vision or 6/60 and 6/24 Snellen and a moderate contraction of their field vision (UK)

Data source	(Inter) National registry for blindness including aetiological factors
Population	general population (0-xyrs of age)
Frequency	ongoing

Nephropathy

Process indicator	percentage of persons with diabetes with serum creatinine measurement in the last 12 months.
Outcome indicator	percentage of persons with diabetes and a serum creatinine level $\geq 400\mu mol/l$
Data collection Population Frequency	see*

Incidence of dialysis and/or transplantation (renal replacement therapy) in patients with diabetes (rate per million general population)

Data source:	(inter)national registries
Validation	unique national number, reimbursement structure

	Diabetes Care system
Population	general population
Frequency	ongoing

Prevalence (stock) of dialysis and/or transplantation (renal replacement therapy) in patients with diabetes (rate per million general population).
This indicator is in most countries available through national or international registries.

Data source	(inter)national registries
Validation	unique national number, reimbursement structure
	Diabetes Care system
Population	general population
Frequency	once yearly

Vascular disease

Indicator	annual incidence of amputations above the ankle in persons with diabetes per 100.000 general population
Definition	Medical, non-traumatical amputation of the leg in a person with diabetes
Data source	hospital discharge records
	ICD 9 250 and
	ICD 1 E10-14, K 72
Validation	DiabCare system
Population	general population
Frequency	once yearly

relevance	yes
validity	yes
comparability	yes
reproducibility/sensitivity	yes
feasibility	probably in most EU

Indicator	Annual incidence of stroke in patients with diabetes per 100.000 general population.

definition	stroke (by WHO) is a focal (or at time global) neurological impairment of sudden onset and lasting more than 24 hrs (or leading to death) and of presumed vascular origin (any permanent neurological brain damage, induced by vascular incidents). (*CAVE eurociss definitions should be taken in to account*)

Data source	HDR code ICD 9 , 250
	Code ICD 10 E10-14. 120-124
Validation	diabcare systems
Population	general population
Frequency	Annually

Indicator	Annual incidence of myocardial infarction in patients with diabetes per 100.000 general population.
Definition	Diagnosis of myocardial infarction is based on clear history, clinical findings and typical laboratory tests or ECG changes (*CAVE eurociss definitions should be taken in to account*)

Data source	HDR code ICD 9 250,
	Code ICD 10 E10-14, 160-169
Validation	diabcare systems
Population	general population
Frequency	Annually

Mortality

Indicator	Annual death rate (per 100.000 population) of persons with on the death certificate as primary or secondary cause of death diabetes mellitus, adjusted for standard European population.

Data source	National registry
Population	General population

Frequency   Ongoing