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Quality and Outcome Indicators for Prevention of Type 2 Diabetes In Europe – IMAGE

REPORT

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IMAGE stands for "Development and **Im**plementation of **a** European **G**uidelin**e** and Training Standards for Diabetes prevention". The general objective of this project is to improve the ability to prevent diabetes in Europe.

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Executive summary

The marked increase of type 2 diabetes necessitates active development and implementation of efficient prevention programmes. A European-level action plan has been initiated in the launch of the IMAGE project to unify and improve the various prevention management concepts which currently exist within the EU. IMAGE stands for "Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention". In addition, to generate guidelines for prevention of type 2 diabetes and to develop a curriculum for the training of prevention managers, one aim of the project is to produce standards for quality management of diabetes prevention programmes.

Even though quality indicators for clinical diabetes care have been developed by several organizations in different countries and continents, data are scarce on quality management of diabetes prevention programmes. Currently, programmes often lack methods for systematic follow-up and evaluation. This report describes the background and the methods used in the development of new quality indicators for diabetes primary prevention programmes. It is targeted at persons responsible for diabetes prevention at different levels within the health care systems.

Development of the quality indicators was conducted by a group of specialists representing different professional groups from several European countries. Indicators were produced by the expert group in consensus meetings and further developed by a subgroup of experts through combining evidence and expert opinion. The final approval and selection of the indicators used a stepwise approval process in which the participants of the other IMAGE working groups gave their comments on the quality indicators before the final selection was made.

The quality indicators were generated to be applicable to the broadest possible population. The definition of high-risk population used here covers all subjects at risk for type 2 diabetes irrespective of the screening method used to identify these individuals. They are designed for adults, but not restricted to any specific age group within the adult population, and are applicable to both sexes. The indicators are linked to the IMAGE guidelines for data standards and are divided into two categories: quality and scientific outcome evaluation indicators. The quality indicators were developed for different prevention strategies: population-level prevention strategies, screening for high risk and high-risk prevention strategies. In total, 22 quality indicators were generated. They constitute the minimum level of quality assurance recommended for diabetes prevention programmes. In addition, 20 scientific evaluation indicators with associated measurement standards were produced. These micro-level indicators describe the measurements which should be used if scientific analysis and reporting are planned. The measurement standards underline the importance of the high quality methodology needed to attain reliable

and comparable results. In addition to the indicators, audit and data collection forms were developed.

The working group hopes that these quality tools together with the IMAGE guidelines and the prevention manager curriculum will provide a useful apparatus for improving the quality of diabetes prevention in Europe, and make different prevention approaches comparable.

1 Objectives

The increase of type 2 diabetes is a major public health problem across the entire European Union (EU). Type 2 diabetes is increasing in prevalence, especially among working-age populations, but also in children and adolescents. Even if the prevalence of obesity were to remain stable until 2030, which seems unlikely, it is anticipated that the number of people with diabetes will more than double (1, 2). Clinical studies have shown that even individuals with a high risk for diabetes can significantly reduce that risk and delay the onset of type 2 diabetes by adopting a healthy, nutritionally balanced diet, increasing physical activity, and maintaining or reducing body weight (3-8). Translating this evidence into practice necessitates active development of efficient prevention strategies and programmes (9). To fulfil this need, action at a European level has been taken by launching the IMAGE project to unify and improve the various prevention management concepts which currently exist across the EU. IMAGE stands for "Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention" and it builds on the results of the EU public health research project DE-PLAN "Diabetes in Europe-Prevention using Lifestyle, Physical Activity and Nutritional Intervention", which relates to the efficient identification of individuals at high risk for type 2 diabetes in the community (10). The objectives of the IMAGE project are: to develop common evidence-based European guidelines for prevention of type 2 diabetes; to develop a European curriculum; and to launch an e-health training portal for the training of prevention managers (PM). Furthermore, the project aims to produce European standards for quality management of these interventions. These actions will form a unique Europe-wide evidence-based guidance system to systematically improve the prevention of type 2 diabetes in Europe (10).

Continuous quality control and evaluation are the key elements of a successful primary prevention programme. Thus, unified quality standards are necessary for systematic evaluation and reporting of prevention programmes in the EU and at a national level (10). Quality indicators for clinical diabetes care have been developed by several organizations and working groups, and have been incorporated into national and international guidelines. The quality management of diabetes prevention programmes is less developed. At present programmes often lack methods for systematic follow-up and evaluation, and there are no standardized European-level quality indicators for diabetes prevention.

This report describes the background and the methods used in the development of the quality tools in the IMAGE project, and presents the European quality indicators for diabetes primary prevention programmes. This report focuses on primary prevention and is targeted at persons responsible for diabetes prevention at different levels within the health care system. The quality indicators are presented

separately for population-level and high-risk prevention strategies. The indicators are further divided into two categories: quality and scientific outcome evaluation indicators. The former constitute the minimum level of quality assurance required in all prevention programmes. Scientific outcome evaluation indicators enhance this process by enabling evaluation of a prevention programme which meets a scientific standard. References to measurement standards for scientific outcome evaluation indicators are provided.

2 Background

2.1 Quality in health care

Quality in health care can be defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (11). However, defining the quality of health care is a complex and not a straightforward issue. For decades, experts have failed to formulate a generally applicable definition (12). Donabedian, a leading expert in the field of health care quality management, has stated that "several formulations are both possible and legitimate" (13). Thus, there are different perspectives on quality and different approaches to measuring and improving it (12). Quality in health care can be divided into different dimensions according to the aspects of care being assessed (14).

Evidence-based clinical guidelines are derived from the practice of evidence-based medicine at the organizational or institutional level. However, the existence of clinical guidelines does not guarantee quality of care. Despite the widespread availability of guidelines and simple screening procedures, a considerable portion of the diabetic population is not properly cared for (15). Indeed, clinical guidelines have been shown to improve clinical practice only when introduced in the context of evaluation (16). As the number of published guidelines is increasing, there has been a need for international standards to improve the development of guidelines. The AGREE consortium has published an appraisal instrument for those who develop guidelines (17).

2.1.1 Quality indicators in clinical care

Diabetes

Despite recommendations, quality issues or indicators are not often incorporated into the clinical guidelines (18). Even the most esteemed international diabetes guidelines commonly lack systematic quality indicators (19-22). However, the National Institute for Health and Clinical Excellence (NICE) (23) have published implementation tools including audit criteria and standards for the guidelines to measure organizational practice against the NICE recommendations (24).

Several projects aiming at enhancing reporting related to diabetes have been conducted at the European level. The European Core Indicators for Diabetes Mellitus (EUCID) project (2006-2007) developed 27 indicators and demonstrated the feasibility of data collection in different EU countries and future member states.

The aim of the project was to promote planning for good diabetes health status and diabetes care organization in each country (25).

Many consortia have developed quality indicators specifically for clinical diabetes care. The OECD Quality Indicator Project has published a list of nine health system level quality indicators for diabetes care (26, 27). In the United States, the Diabetes Quality Improvement Project (DQIP) has developed and implemented a widely accepted and comprehensive set of national measures for evaluation (28). A working group including participants from 15 EU/EFTA countries has generated an indicator set composed of 31 indicators for monitoring diabetes and its complications within EU/EFTA countries (29). In several European countries efforts have been made to implement quality indicators in diabetes care. In Saxony, Germany, the Saxon Diabetes Management Programme has developed an integrated quality management system (30). A Belgian study has produced a list of quality indicators for type 2 diabetes by evaluating 125 diabetes guidelines in five European countries (18). One group from the Netherlands provided a set of quality indicators for the pharmacological management of type 2 diabetes (31). In the field of diabetes education, the International Diabetes Federation has published standards including quality indicators (32, 33).

Cardiovascular diseases

Quality measures are not incorporated into the principal European cardiovascular clinical guidelines (34). In the USA, quality indicators are not built into guidelines; however, the American Heart Association and the American College of Cardiology have launched an initiative to develop performance measures for health care providers (35). This effort is intended to promote the implementation of clinical evidence guidelines. These performance measures are derived from practice guidelines.

2.1.2 Quality indicators in health promotion and primary prevention

The OECD Quality Indicator Project has produced a set of 27 indicators covering primary care, prevention, and health promotion in general (36). The objectives of the project are to develop measures for evaluating the performance of primary care.

Diabetes

Even though quality indicators for clinical diabetes care have been developed by several organizations in different countries and continents, data are scarce on quality management in diabetes prevention programmes. At present, programmes

often lack methods for systematic follow-up and evaluation. No unified European level quality indicators for diabetes prevention programmes have been published.

Obesity

Many national organizations and consortia (37-39), have developed guidelines for prevention and management of obesity. However, only the NICE recommendations on obesity (40) include audit criteria, to help in the implementation of the guidelines, and identify measurable indicators (41).

Cardiovascular diseases

Like the diabetes guidelines, the European Society of Cardiology guidelines on cardiovascular disease prevention in clinical practice (22) and on diabetic heart disease (20) lack quality indicators. The American College of Cardiology Foundation/American Heart Association, in collaboration with other organizations, have recently published performance measures for the primary prevention of cardiovascular disease in adults (42) as well as a curriculum on the prevention of cardiovascular disease (43). The objectives of the performance measures are to provide practitioners and institutions with tools for measuring the quality of care and to identify opportunities for improvement (42). The aim of the publication of the performance measures is to promote the implementation of clinical evidence guidelines (21). The performance measure set includes 13 indicators, but specific performance measures for diabetes were developed in the recent work of the National Diabetes Quality Improvement Alliance. Previously, in Europe, a set of quality indicators for the prevention and management of cardiovascular disease in primary care was developed by experts representing nine European countries (44). This set of indicators incorporates 44 quality indicators, of which several are specifically related to diabetes (44).

2.2 Developing indicators

2.2.1 Characteristics of quality indicators

In the field of health care, methods of measuring and evaluating performance are under active development. Indicators can be defined in several ways. In general, they are evidence-based measures that assess a particular health care structure, process or outcome (13). Indicators provide a quantitative base for organizations, planners and service providers to improve processes and care (45). They generate a solid and integrated overview of a variety of quality dimensions and aspects; however, they are not direct measures of quality, which is a multidimensional

phenomenon (45). Indicators are most useful when the processes and outcomes they relate to can be influenced by clinical interventions (46).

A good indicator is meaningful, scientifically sound and interpretable (47). It can be described by the following key characteristics (45): based on agreed definitions, a good indicator is highly specific and sensitive, valid and reliable, discriminates well, relates to clearly identifiable events for the user, permits useful comparisons and is evidence-based.

To measure quality in a reliable way presupposes that criteria and standards are based on a scientifically validated fund of knowledge (48) or at least on the most authoritative opinion in any particular subject area (13). A valid indicator must be reproducible and consistent. Indicators vary in their validity and reliability. Validity is the degree to which the indicator measures what it is intended to measure, i.e. it occurs when the result of a measurement corresponds to the state of the phenomenon which is being measured (45). Reliability is the extent to which a measurement with an indicator is reproducible. Reliability is important when using an indicator to make comparisons among groups or within groups over time (45). Even though it is not possible to develop an error-free measure of quality, an indicator should always be tested for feasibility, reliability and validity during the development phase (49). When using quality indicators it should be borne in mind that "indicators just indicate" and that even the best indicators have limitations. When conclusions are drawn based on quality indicators, the limitations of the indicators should be taken into consideration.

2.2.2 Methods for indicator development

Indicators can be developed using systematic or non-systematic methods (49). Non-systematic methods are not evidence-based and indicators developed in this way may be less credible than those produced using systematic methods. Systematic methods are based on scientific evidence and guidelines (49). Often scientific evidence and expert opinion are combined, as in some fields evidence may be too scarce to be solely used. Several types of consensus methods are available for gathering expert opinion (49). These include consensus development conferences (50), the Delphi technique (49), the nominal group technique (49), the RAND appropriateness method (51), and iterated consensus rating procedures (49).

2.2.3 Classification of indicators

Indicators may be classified in several ways (45). In the field of prevention, the indicators may cover different prevention strategies such as the population-level or high-risk strategies, at different levels of the health care system: individual (micro), health system (meso) or societal (macro) level. Indicators can also be categorized by function, such as screening, intervention or monitoring. Generic indicators can be used in different kinds of settings within the health care system, while disease-specific indicators are relevant only for a specific disease. An indicator may be either rate-based or sentinel. A rate-based indicator is expressed in terms of proportion or of rates. A sentinel indicator relates to individual events or phenomena.

The quality assessment theory by Donabedian is called the structure/process/outcome (SPO) or the Donabedian's Triad Model (13, 52). This theory comprises three quality elements: structure, process and outcome. Structure describes the material and human resources as well as the organizational structure. This includes facilities, financing, equipment and personnel. Process relates to activities undertaken to achieve objectives, such as activities related to the giving and receiving of care or the implementation of interventions. Outcome describes the effect of care or interventions on the health status of a subject or population. Outcomes can be expressed in terms of 'The five Ds': (i) death: a bad outcome if untimely; (ii) disease: symptoms, physical signs, and laboratory abnormalities; (iii) discomfort: symptoms such as pain, nausea, or dyspnoea; (iv) disability: impaired ability in relation to usual activities at home, work, or in recreation; and (v) dissatisfaction: emotional reactions to disease and its care, such as sadness and anger (11).

Outcome indicators can be divided into intermediate and end-result indicators (45). Some end-result indicators, such as survival, may only be assessed after several years (45). Intermediate outcome indicators describe changes in biological status that are closely correlated or associated with end-result outcomes (e.g. HbA1c or microalbuminuria in diabetes). The first two elements, structure and process, are indirect measures that influence the outcome. All elements are linked with each other. Outcome indicators seem to provide the best view of quality performance, but process indicators are much more sensitive and unequivocal in the measurement of changes in quality values (45). This structure/process/outcome approach to quality assessment is possible only because good structure increases the likelihood of good process and good process increases the likelihood of good outcome (13).

3 Methodology

3.1 Process of developing indicators

Development of the IMAGE quality management system including quality indicators was conducted by a group of specialists representing different professional groups from several European countries. Members of the group have been actively involved in pivotal studies on diabetes prevention such as the Diabetes Prevention Study (DPS) and have extensive experience in the implementation of diabetes prevention programmes within the community. The members of the IMAGE Working Group and IMAGE Study Group are listed in Appendix 1.

The development of the quality management processes and quality indicators was based on combining evidence and expert opinion. Indicators were produced by the expert group in consensus meetings and further developed by a subgroup of experts. The working group reviewed the existing scientific evidence in the field. Based on that knowledge, measurement specifications were designed and the standards of the indicator described. Initially, 109 quality indicators were developed. Further selection revealed 22 key quality indicators. In addition, 20 scientific outcome evaluation indicators were developed. This process included detailed group discussions and additional literature surveys and followed the principles presented in Section 2.2. The final approval and selection of the indicators was carried out using a stepwise approval process in which the participants of the other IMAGE Working Groups gave their comments on the quality indicators before final selection.

3.2 Defining target population

The IMAGE quality indicators are presented separately for population-level and high-risk prevention strategies as well as for screening for high risk. The population-level prevention strategy aims to improve, develop and implement primary prevention programmes and activities targeting the entire population. From a societal perspective, this is not the sole responsibility of the health care sector. Successful population-level prevention of diabetes involves the participation of different community stakeholders such as decision makers, the education system, the food industry, the media, urban planners, and non-governmental organizations.

Screening for individuals at high risk for type 2 diabetes is essential for successful interventions. Different methods to screen for high-risk individuals

include the use of risk questionnaires, opportunistic screening and computer database searching. Each country and organization has to develop and introduce a method suitable for its local needs and resources.

Clinical studies have consistently shown that diabetes can be prevented, or at least postponed, by lifestyle changes related to healthy nutrition, an adequate amount of physical exercise and weight reduction (3-8). In addition to lifestyle changes, drugs such as metformin, acarbose, orlistat and thiazolidinediones can reduce the relative risk of diabetes in high risk individuals with impaired glucose tolerance (5, 7, 53-57).The aim of the high-risk prevention strategy is to identify high-risk individuals and support them in adopting the lifestyle changes required to reduce their risk for diabetes and other vascular risk factors.

The quality indicators were generated to be applicable to the broadest possible population. The definition of high-risk population used here covers all subjects at risk for type 2 diabetes irrespective of the screening method used to identify these individuals. The indicators are designed for adults, but not restricted to any specific age group within the adult population, and are applicable to both sexes, but may not be applicable to different ethnic groups.

3.3 Classification of indicators

3.3.1 Structure, process, outcome model

The IMAGE quality indicators are classified according to the structure/process/outcome (SPO) model (13, 52) modified so that, for practical reasons, the structure/process indicators are presented in combination. The structure/process indicators constitute the quality criteria for diabetes prevention while the outcome indicators focus on outcome evaluation and monitoring. Thus indicators belong either to structure/process or outcome categories. The latter include both intermediate and end-result indicators as appropriate for the setting. Intermediate outcome indicators reflect changes in biological status and may be regarded as short-term outcomes (46).

The structure/process quality indicators are aimed at internal quality assurance and can be used as a check-list when planning and conducting a prevention programme. They therefore enable comparisons between different programmes and also between health care providers conducting these activities.

3.3.2 Macro, meso and micro levels

Indicators are meant for users operating at several different levels of the health care system. At the macro level, indicators are developed to be utilized by national-level decision makers whose role it is to generate the prerequisites for diabetes/obesity prevention. This means, for example, representatives of the national-level health institutes or non-governmental organizations.

The level of operative primary health care is called the meso level. Depending on the country, indicators may be used by individuals responsible for activities related to diabetes prevention in municipalities, health districts, health care centers, occupational health, the private sector or local-level non-governmental organizations.

At the micro-level, the indicators are meant for use by the personnel who execute the actual preventative work. This may be a physician, nurse, dietician, physiotherapist or prevention manager.

The IMAGE quality indicators are categorized so that the population-level prevention strategy indicators include both macro- and meso-level indicators. Screening for high-risk indicators is applicable to the meso level, and that for the high-risk prevention strategy indicators applicable to the meso and micro levels.

3.3.3 Quality and scientific outcome evaluation indicators

The IMAGE indicators are divided into quality and scientific outcome evaluation indicators. Quality indicators are the minimum requirement to be considered when conducting prevention activities according to the level of the operator. An additional set of indicators, scientific outcome evaluation indicators, is provided for scientific evaluation purposes. Further, measurement standards for scientific outcome evaluation are provided.

Table 1 presents an overview of classifications and end results of the IMAGE quality and outcome indicators.

3.4 Target value assignment

In previous quality indicators projects it has been concluded that it is difficult to set any target values for the indicators at the European level due to different health care systems and varying national recommendations. A direct transfer of indicator target values is not always possible between countries (58). Despite this, our aim was to assign target values for micro-level quality indicators. This applied to the

high risk prevention strategy indicators for which accurate micro-level objectives could be extracted based on scientific data from clinical intervention studies, especially from the DPS study (3, 4).

Table 1. Overview of classification of IMAGE quality and outcome indicators

PREVENTION STRATEGY	
Population strategy	Activities aimed at promoting the health of entire population
Screening for high risk	Identification of at-risk individuals
High-risk intervention strategy	Interventions on identified at-risk individuals
LEVEL OF HEALTH CARE OPERATOR	
Macro level	National-level decision makers
Meso level	Operative primary health care level
Micro level	Individual-level prevention work
QUALITY CRITERIA	
Structure indicators	Material and human resources, organizational structure
Process indicators	Activities undertaken to implement intervention
QUALITY AND OUTCOME INDICATORS	
Outcome indicators	Effects of interventions and activities related to diabetes prevention
Scientific evaluation indicators	Outcome measures for evaluation purposes
RECOMMENDATIONS AND TOOLS	
IMAGE audit tools	All quality criteria and indicators, and scientific evaluation indicators to be used to measure current practice in diabetes prevention against the IMAGE guideline recommendations (Appendix 2)
Scientific evaluation tool	The scientific evaluation indicators and corresponding recommendations for measurement protocols and references (Appendix 3)
Data collection form	An example of the content that is recommended for adaptation into local versions of the data collection forms at the micro level of diabetes prevention (Appendix 4)

4 Results

4.1 Quality indicators for diabetes prevention

4.1.1 Population-level prevention strategies

At the macro level, a prerequisite for the desired outcome in population-level prevention strategies is that policies and legislation support an environment favouring diabetes prevention. In addition, each country should have a national diabetes prevention plan in which specific prevention targets are defined. These targets should include consideration of the special needs of ethnic minorities and underprivileged socio-economic groups. Furthermore, policies and legislation should take into account the specific measures needed for prevention of obesity among children and adolescents. To enable these tasks to be accomplished, national health monitoring systems should provide sufficient information for conducting efficient surveillance.

At the health care provider level, procedures should support health promotion including diabetes prevention. The health care provider should allocate sufficient resources to preventative work. Basic knowledge regarding population-level prevention of diabetes/obesity/cardiovascular diseases should be included in the curricula of the medical professionals employed by the health care provider. There should also be active collaboration between the different stakeholders active in the field of health promotion.

In addition to the above-mentioned quality criteria relating to structure and process, a list of outcome indicators was generated during the course of the IMAGE work (Table 2). With these indicators at hand, decision makers can monitor and evaluate the quality and effectiveness of the selected population-level strategies.

Table 2. Outcome quality indicators for population-level prevention strategies at macro and meso levels

MACRO-LEVEL OUTCOME INDICATORS
Proportion of population aware of diabetes and its risk factors.
Prevalence of diabetes in the population.
Percentage of the population physically inactive.
Prevalence of overweight, obesity and abdominal obesity in population.
Percentage of population following national recommendations on nutrition.
Percentage of health care costs allocated to prevention programmes.
MESO-LEVEL OUTCOME INDICATORS
Proportion of health care personnel per health care provider active in population level primary prevention.
Number of health promotion organizations active in population level primary prevention.

4.1.2 Screening for high risk

Screening is an essential part of the high-risk prevention strategy. In addition, screening protocols can be designed so that they also support population-level prevention activities by increasing awareness of the disease. Different screening protocols should be validated and evaluated at a national level. The selected protocols and strategies should be implemented by the health care provider. The screening protocol used should contain a pathway for diagnostic procedures, as well as defined intervention strategies for the different subgroups (age, minority status etc.). The health care provider should promote validated diabetes risk assessment tools. Information technology systems should support the implementation of screening.

Depending on the health care system, these indicators can be the responsibility of either macro- or meso-level operators. For this reason, the audit tool to monitor these quality criteria is given in Appendix 2. In addition, the indicators in Table 3 were identified as outcome indicators for screening for high risk.

Table 3. Outcome quality indicators for screening for high risk

MESO-LEVEL OUTCOME INDICATORS
Proportion of the population screened by health care providers per year.
The percentage of identified high-risk individuals directed to diagnostic procedures.
The percentage of identified high-risk individuals directed to lifestyle interventions.

4.1.3 High-risk prevention strategies

At meso level, every screening strategy should incorporate clinical pathways in the organization of the health care provider to deal with individuals at risk for diabetes. The health care provider should support a multidisciplinary approach for interventions. High-risk prevention strategies should be included in the education of healthcare professionals. The medical record system should support interventions and chronic disease prevention in general.

At micro level, the individual's risk factor profile should be assessed at the beginning of the intervention process, and the motivation for behavioral changes explored. Structure and content of the interventions should be defined and individualized targets for interventions established. Plans for individual follow-up should be defined and recorded. An audit tool (Appendix 2) includes quality criteria related to these elements of structure and process.

The indicators in Table 4 were identified as outcome indicators corresponding to the structures and processes above at meso and micro levels.

Table 4. Outcome quality indicators for high-risk prevention strategies at meso and micro levels

MESO-LEVEL OUTCOME INDICATORS
Number of healthcare professionals at health care provider level qualified for interventions per 100.000 inhabitants.
The percentage of remitted high risk individuals participating in lifestyle interventions.
Proportion of individuals dropping out of interventions.
Proportion of high-risk individuals in interventions achieving clinically significant changes in risk-factors at 1 year follow-up.
Diabetes incidence rate among high-risk individuals in interventions by health care provider.
MICRO-LEVEL OUTCOME INDICATORS
Proportion of planned intervention visits completed over 1 year.
Weight change over 1 year.
Change in waist circumference over 1 year.
Change in glucose level over 1 year.
Change in the quality of nutrition over 1 year.
Change in physical activity over 1 year.

In addition to the quality indicators related to the high risk intervention strategy at micro-level, target values which correspond to the indicators were identified. In the DPS study (3), the following targets were applied: a 5% or greater reduction in weight, 30 minutes or more of moderate intensity daily, a dietary fat level of less than 30 E%, saturated fat less than 10 E%, and an intake of fiber of 15g/1000 kcal (15g/4200 KJ) or more. These targets may be taken into consideration when planning micro-level diabetes prevention. However, intervention targets should be individualized and founded on the baseline evaluation.

4.2 Scientific outcome evaluation indicators for diabetes prevention

Table 5 presents the recommended scientific evaluation indicators to be used as outcome measures in the scientific evaluation of a diabetes prevention programme.

To obtain reliable results, measurements and methods used in the diabetes prevention programmes should be standardized and valid. Table 5 provides the references for the recommended measurement protocols for the scientific outcome evaluation indicators (presented also in Appendix 3).

The standards related to physical measurements (weight, height, waist circumference, blood pressure) can be found in the Feasibility of European Health

Examination Survey (FEHES) recommendations (62) and in the World Health Organization (WHO), STEPS Manual (63). The FEHES recommendations also include a questionnaire on smoking habits (62).

Recommendations on blood sampling and lipid measurements are available in the recommendations both of FEHES (62) and of the U.S. Center for Disease Control and Prevention (CDC) (73) which has a certification programme for lipid measurements.

The WHO Laboratory Diagnosis and Monitoring of Diabetes Mellitus 2002 document (64) provides standards for glucose measurements including the oral glucose tolerance test (OGTT). Diagnosis of diabetes and risk assessment is based on fixed cut-off points. For this reason all steps in the analytical process require attention (59). It is important to notice that preanalytical issues may seriously affect the quality of the glucose assays. Glucose is lost through glycolysis and NaF has been used for decades to inhibit glycolysis. In addition, ice slurry is often used to prevent preanalytic loss of glucose. However, new Fluoride-Citrate mixture tubes allow prolonged storage and transport of the samples and their adoption should be considered to assure a high quality measurement process (59, 60). Even though the expectation is that this would improve the precision of glucose measurements, it may also increase the number of individuals diagnosed with diabetes unless compensatory changes in diagnostic cut-off points are made (59).

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) have published standards for HbA1c measurements (32, 33) . Major differences exist in commercially available insulin assays. An IFCC working group on the Standardization of Insulin Assays has been jointly established with the American Diabetes Association and is currently developing a candidate reference method for insulin analysis.

There is no consensus on what constitutes adequate measurement and documentation of physical activity or nutrition. Dietary pattern and composition can be evaluated using several methods: food diary, food frequency questionnaire, and checklist. The selection of a method depends on availability, the cultural background, and the resources and level of cooperation of the high-risk individual. For accurate calculation of nutrient intakes, culturally specific food composition databases are mandatory. The quality of diet in relation to recommendations and dietary changes can also be assessed on the basis of frequency of consumption of recommendable (e.g., vegetables, fruit, whole grains) and non-recommendable (e.g. soft drinks, pastries) food items.

Accurate methods to measure physical activity are pedometers and accelerometers. Self-reported data can be collected via interviews, diaries, and recalls. Assessment of physical activity should include: type of activity (e.g., walking, swimming), frequency (number of sessions), duration, and intensity

(level of physical effort). Using these four components, relative energy expenditure can be estimated, often referred to in terms of metabolic equivalents (METS) (61).

The European Health Interview Survey (EHIS) (74) includes standardized questions on use of medications. Issues related to health economic evaluation and the costs are presented in the IMAGE Scientific Guidelines. Quality of life should be measured with standardized instruments such as WHO-5 (75), SF-36 (76) , SF-12 (77) 15-D (78) and possible translations should be certified. Treatment satisfaction can be measured, for example, by using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) (79).

Table 5. Scientific outcome evaluation indicators and measurement recommendations

INDICATOR	UNIT	REFERENCE
Body weight, kg	kg	FEHES (62), WHO STEPS (63)
BMI	kg/m^2	FEHES (62), WHO STEPS (63)
Waist circumference	cm	FEHES (62), WHO STEPS (63)
Fasting and 2h OGTT glucose	mmol/l	WHO (59, 60, 64)
HbA1c	%	IFCC (32, 33)
Fasting insulin	mU/l	IFCC (65)
Total energy intake	kcal/day	IMAGE Toolkit (66, 67, 82)
Fat intake	E%	IMAGE Toolkit (66, 67, 82)
Saturated fat intake	E%	IMAGE Toolkit (66, 67, 82)
Fibre intake	g/1000 kcal	IMAGE Toolkit (66, 67, 82)
Physical activity	METS	(61, 68-72)
Fasting total HDL and LDL cholesterol	mmol/l	FEHES (62), CDC (73)
Fasting triglycerides	mmol/l	FEHES (62), CDC (73)
Systolic and diastolic blood pressure	mmHg	FEHES (62), WHO STEPS (63)
Smoking habits		FEHES (62)
Drug treatments		EHIS (74)
Costs	€	IMAGE Scientific Guidelines (83)
Quality of life	Score	WHO-5 (75), SF-36 (76) , SF-12 (77) 15-D (78)
Treatment satisfaction	Score	DTSQ (79)

4.3 Audit tools for diabetes prevention

All the structure, process and outcome indicators developed in the IMAGE group are included in the IMAGE audit tool (Appendix 2). The quality criteria for the audit tool comprise structure and process indicators. Where possible, the corresponding chapter in the IMAGE scientific guidelines is identified. In addition, outcome quality indicators are presented for the outcome evaluation.

Audit tools were specifically developed for operators working at different levels in health care, i.e., at macro, meso and micro levels. The audit tools can be used to measure current practice in diabetes prevention against the IMAGE guideline recommendations.

4.4 Micro-level data collection form

The data collection form is an example of the content that is recommended for inclusion and adaptation into local versions of the data collection tools for the micro-level diabetes prevention. However, local needs and circumstances necessarily shape the final structure of the data collection form applied in different prevention programmes.

5 Discussion

As part of the IMAGE project, a set of quality and scientific outcome evaluation indicators for diabetes prevention programmes were developed along with the IMAGE Evidence-Based Guideline (83) and the accompanying IMAGE Toolkit for prevention of type 2 diabetes (82). Therefore, the indicators are closely linked to the guideline standards and are intended to be used in conjunction with the guidelines. The quality indicators are aimed to provide European decision makers, health care providers and health care personnel working in prevention activities with the tools to monitor, evaluate and improve the quality of diabetes prevention. In addition, standards of measurements for scientific outcome indicators were identified, with a view to reporting on clinical trials and effectiveness research across Europe, thus enabling comparisons between different study groups.

Both individual and population-level prevention strategies were taken into account when developing the indicators. The quality indicators were selected to represent different dimensions of preventative work: population-level prevention strategy, screening for high risk, and high-risk prevention strategy. To promote the usability of the indicators, they were generated to be applicable to the broadest possible population. The definition of high-risk population used covers all subjects at risk for developing type 2 diabetes irrespective of the screening method used to identify these individuals.

Population-level prevention strategies and macro-level quality indicators address the close link between type 2 diabetes, obesity and cardiovascular diseases. Some of the macro-level outcome indicators require data that can only be obtained through population-based health surveys. The Feasibility of a European Health Examination Survey (FEHES) collaboration (80), another EU-funded project, provides recommendations for organizing standardized health surveys. Further, population-level standardized data may be available in the future through the EUBIROD collaboration (81).

Meso-level screening for high risk and high risk prevention strategy indicators assess quality and outcome at the health care provider level. The structure/process quality indicators (i.e. the quality criteria) may be used as internal quality assurance tools at the health care provider level when planning and conducting a prevention programme. The outcome quality indicators serve both as internal and external quality measures and enable comparisons between different programmes and organizations.

Within high-risk prevention strategies, micro-level indicators address the quality of prevention at individual level. Target values for micro-level quality indicators are defined if there exists scientific evidence to support the values. These indicators serve as a quality tool for individual health care professionals.

The quality indicators are intended to be used in a prospective setting, but may also be applicable for retrospective analysis if the quality of data collection allows this. Used alone, they comprise the minimum level of quality standards. Individuals and organizations using these measures are encouraged to involve the scientific evaluation perspective in their preventative work by using the scientific outcome evaluation indicators and related instruments described in the measurement standards section. High quality methodology is essential to attain reliable and comparable results.

Audit tools were specifically developed to measure current practice in diabetes prevention against the IMAGE guideline recommendations. As the responsibility for the implementation of the guidelines differs depending on national and local legislation, their implementation may need adaptation to local regulations and circumstances. At the micro level, individual targets should be based on individualized baseline evaluation.

Even though data from the pivotal diabetes prevention studies have proved the efficacy of preventative interventions, less data are available on the effectiveness of implementation of diabetes prevention in the everyday work of primary health care practitioners. Thus, the development of the quality management processes and quality indicators was based on combining evidence and expert opinion. Some limitations related to the development process should be noted.

Even though the quality indicators are linked to the IMAGE Evidence-Based Guideline data standards, target value assignment was difficult because of lack of data on the general population. It should be noted that target values related to weight reduction, nutrition, and physical activity for micro-level quality indicators are drawn from the DPS study, which was conducted in obese individuals with impaired glucose tolerance. The working group recognizes that some of the indicators are based mainly on expert opinion as randomized controlled trials are more difficult to conduct than pharmaceutical trials, and thus the number of trials remains limited.

Earlier experiences from other projects have revealed challenges in reaching consensus between countries with different cultural traditions and health care systems. A working group with representatives of 15 EU/EFTA countries has compiled a list of EU-level diabetes indicators (29). The work was considered challenging due to differences in data availability; eleven out of 15 countries could not provide any data. Similarly, experts in the field of cardiology have reported particular problems related to the development of European-level quality indicators for cardiovascular primary care (44). In the IMAGE project, detailed group discussions within the working group responsible for quality indicator development were followed by a stepwise approval process.

6 Conclusions

Parallel with the development of the IMAGE Evidence-Based Guideline and IMAGE Toolkit for the prevention of type 2 diabetes, a quality management system with quality and scientific outcome evaluation indicators and audit tools was developed. The indicators are presented according to the different levels of the health care system, and they can be used for internal quality control as well as for external comparison between operators by using the audit tools. These quality tools complement the IMAGE Evidence-Based Guideline and IMAGE Toolkit and the prevention manager curriculum, and will hopefully provide a useful tool for improving the quality of diabetes prevention in Europe.

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Appendix 1. IMAGE Study Group

IMAGE QUALITY AND OUTCOME INDICATORS WORKING GROUP

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IMAGE Study Group:

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Appendix 2. IMAGE Quality audit tools

MACRO-LEVEL POPULATION PREVENTION STRATEGY QUALITY CRITERIA AND QUALITY INDICATORS

TYPE	QUALITY CRITERIA	CRITERIA MET		IMAGE REFERENCE
S/P	Policies and legislation support environment favouring diabetes prevention.	Yes	No	EBG
S/P	A national diabetes prevention plan with specific prevention targets is available.	Yes	No	EBG
S/P	National health monitoring systems provide sufficient information for the surveillance of diabetes.	Yes	No	EBG
S/P	In all activities of diabetes prevention, ethnic minorities and low socio-economic groups are considered.	Yes	No	EBG
S/P	Policies and legislation take into account measures needed for prevention of obesity among children and adolescents.	Yes	No	EBG
TYPE	**QUALITY INDICATOR**	**DATA AVAILABLE**		**DATA SOURCE**
O	Proportion of population aware of diabetes and its risk factors.	Yes	No	
O	Prevalence of diabetes in the population.	Yes	No	
O	Percentage of the population physically inactive.	Yes	No	
O	Prevalence of overweight, obesity and abdominal obesity in population.	Yes	No	
O	Percentage of population following national recommendations on nutrition.	Yes	No	

EBG = IMAGE Evidence-Based Guideline.
Data source = Identify the source of data for respective outcome indicator.
O = Outcome indicators.
S/P = Structure/Process indicators.

**MESO-LEVEL POPULATION, SCREENING AND HIGH RISK INTERVENTION STRATEGIES
QUALITY CRITERIA AND QUALITY INDICATORS**

TYPE	QUALITY CRITERIA	CRITERIA MET		IMAGE REFERENCE
S/P	Basic knowledge in population-level prevention of diabetes is part of the curricula of medical professionals working for health care provider.	Yes	No	
S/P	Health care providers are collaborating actively with other players active in health promotion.	Yes	No	EBG
S/P	Different screening protocols have been evaluated at national level.	Yes	No	EBG
S/P	Validated diabetes risk assessment tools are available to health care providers.	Yes	No	EBG
S/P	Information technology systems supporting the implementation of screening are available at health care provider level	Yes	No	EBG
S/P	Defined clinical pathways exist for the health care provider to deal with individuals at risk for diabetes.	Yes	No	EBG
S/P	Multidisciplinary approach for interventions is supported by the health care provider.	Yes	No	EBG
S/P	High-risk prevention strategies are included in the education of the health care professionals.	Yes	No	
S/P	Medical record system supports interventions for chronic disease prevention.	Yes	No	
TYPE	**QUALITY INDICATOR**	**DATA AVAILABLE**		**DATA SOURCE**
O	Proportion of health care personnel per health care provider active in population level primary prevention.	Yes	No	
O	Number of health promotion organizations active in population level primary prevention.	Yes	No	
O	Proportion of the population screened by health care provider per year.	Yes	No	
O	The percentage of identified high-risk individuals remitted to diagnostic procedures.	Yes	No	
O	The percentage of identified high-risk individuals remitted to lifestyle interventions.	Yes	No	
O	Number of healthcare professionals at health care provider level qualified for interventions per 100.000 inhabitants.	Yes	No	
O	The percentage of remitted high-risk individuals participating in lifestyle interventions.	Yes	No	
O	Proportion of individuals dropping out of interventions.	Yes	No	
O	Proportion of high-risk individuals in interventions achieving clinically significant changes in risk factors at 1 year follow-up.	Yes	No	
O	Diabetes incidence rate among high-risk individuals in interventions at health care provider.	Yes	No	

EBG = IMAGE Evidence-Based Guideline.
Data source = Identify the source of data for respective outcome indicator.
O = Outcome indicators.
S/P = Structure/Process indicators.

MICRO-LEVEL HIGH RISK INTERVENTION STRATEGY QUALITY CRITERIA AND QUALITY INDICATORS

TYPE	QUALITY CRITERIA	CRITERIA MET		IMAGE REFERENCE
S/P	Individual's risk factor profile is assessed.	Yes	No	IMAGE Toolkit
S/P	Individual's motivation for behavioural changes is discussed.	Yes	No	IMAGE Toolkit
S/P	Structure and content of the interventions have been defined at individual level.	Yes	No	IMAGE Toolkit
S/P	Individualized targets for interventions have been established.	Yes	No	IMAGE Toolkit
S/P	Plan for follow-up is defined.	Yes	No	IMAGE Toolkit
TYPE	**QUALITY INDICATOR**	**DATA AVAILABLE**		**DATA SOURCE**
O	Proportion of planned intervention visits completed over 1 year.	Yes	No	
O	Weight change over 1 year.	Yes	No	
O	Change in waist circumference over 1 year.	Yes	No	
O	Change in glucose over 1 year.	Yes	No	
O	Change in the quality of nutrition over 1 year.	Yes	No	
O	Change in physical activity over 1 year.	Yes	No	

Data source = Identify the source of data for respective outcome indicator.
O = Outcome indicators.
S/P = Structure/Process indicators.
IMAGE Toolkit = IMAGE Toolkit for the Prevention of Type 2 Diabetes in Europe.

Appendix 3. IMAGE Scientific evaluation tool

SCIENTIFIC EVALUATION TOOL

EVALUATION INDICATORS, UNITS OF MEASUREMENTS AND RECOMMENDED MEASUREMENT PROTOCOLS

INDICATOR	UNIT	REFERENCE
Body weight, kg	kg	FEHES (1), WHO STEPS (2)
BMI	kg/m^2	FEHES (1), WHO STEPS (2)
Waist circumference	cm	FEHES (1), WHO STEPS (2)
Fasting and 2h OGTT glucose	mmol/l	WHO (3-5)
HbA1c	%	IFCC (6, 7)
Fasting Insulin	mU/l	IFCC (8)
Total energy intake	kcal/day	IMAGE Toolkit (9, 10, 24)
Fat intake	E%	IMAGE Toolkit (9, 10, 24)
Saturated fat intake	E%	IMAGE Toolkit ((9, 10, 24)
Fibre intake	g/1000 kcal	IMAGE Toolkit (9, 10, 24)
Physical activity	METS	(11-16)
Fasting total HDL and LDL cholesterol	mmol/l	FEHES (1), CDC (17)
Fasting triglycerides	mmol/l	FEHES (1), CDC (17)
Systolic and diastolic blood pressure	mmHg	FEHES (1), WHO STEPS (2)
Smoking habits		FEHES (1)
Drug treatments		EHIS (18)
Costs	€	IMAGE Evidence-Based Guideline (25)
Quality of life	Score	WHO-5 (19), SF-36 (20) , SF-12 (21), 15-D (22)
Treatment satisfaction	Score	DTSQ (23)

Recommended measurement protocols for scientific outcome indicators

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Appendix 4. IMAGE Micro-level data collection form

RECOMMENDED CONTENTS TO BE INCLUDED AND ADAPTED IN THE LOCAL VERSIONS OF THE DATA COLLECTION FORMS TO SUPPORT, MONITOR AND EVALUATE MICRO-LEVEL DIABETES PREVENTION

	CORE ITEMS	**ADDITIONAL ITEMS**
1. Personal data	– Personal identification	– Marital status – Education – Ethnicity – Employment status
2. Screening	– Method used in screening – Risk score type and result (if used) – Reason for intervention	
3. Health and health behaviour	– Chronic diseases – Regular medications – Smoking: Never/previously/currently – Physical activity: Type, frequency, intensity Method used in measuring (for example: interview, diary, recall, pedometers, accelerometers) – Nutrition: Dietary pattern: consumption of vegetables, fruits, spreads and oil, bread and cereal (whole / refined grain), sweets, beverages, alcohol e.g. Method used in measuring (for example: food diary, food frequency questionnaire or checklist)	– Family history of diabetes and CVD How often, products used Work-related, commuting, leisure Energy proportion (E%) of fat, saturated and trans fat, dietary fiber (g / day, g / 1000 kcal), total energy, alcohol (g, E%), added sugar (g, E%)
4. Clinical data (measured)	– Body weight – Body height – Waist circumference – Fasting glucose – Systolic and diastolic blood pressure	– 2 hour OGTT glucose – HbA1c – Lipids (total, LDL, HDL cholesterol and triglycerides) – Additional measures (fasting insulin etc)
5. Content of the intervention	– Type of intervention (group, individual etc.) – Frequency, duration and other details – Targets for the intervention: Weight, diet, smoking, physical activity – Reinforcement	
6. Success of the intervention	– Adherence (proportion of planned intervention visits completed) – Changes in: health and health behavior (item 3) and clinical data (item 4)	– The Diabetes Treatment Satisfaction Questionnaire: DTSQ – Health related quality of life
7. Maintenance	– Plans how to sustain possible lifestyle changes after intervention	