B.I.R.O.

Best Information through Regional Outcomes

A Public Health Project funded by the European Commission, DG-SANCO 2005

WP 2: CLINICAL REVIEW

INDICATOR DEVELOPMENT

Results

January 2009

Institute of Medical Technologies und Health Management
JOANNEUM RESEARCH Forschungsgesellschaft mbH
Elisabethstraße 11a
8010 Graz
Austria

Table of contents

1. Aim

The aim of the „BIRO - Best Information through Regional Outcomes : a Shared Evidence-Based Diabetes Information System to Support European Health Policy“ project is to provide an ad hoc, evidence and population-based information system for diabetes, to support prevention, coordinated care and outcomes management on a continuous basis.

The aim of this clinical review is to give an overview of the existing literature in order to propose a set of relevant measures collected routinely at the provider level that can also be used for benchmarking of diabetes prevention and care in the different European health care systems.

2. Methodology

This document consists of three main sections which reflect the working process of clinical review and indicator development.

In a first step existing guidelines were viewed. Comments, literature references and potentially interesting data items were extracted and clustered in thematic area Reference numbers appear in the order of their respective original documents. The results of this first phase are aggregated in the "Data Items for Thematic Areas" section. A data item per definition is "one single piece of data" or "the smallest piece of information that can be obtained from a survey or census". As several data items were not yet covered by existing indicators, several new or modified ones were suggested.

In a second step indicators were defined, whereby indicators are seen as "a measure used to determine, over time, performance of functions, processes, and outcomes". The selection of indicators was carried out along the recommendations for indicator evaluation developed by the US Institutes of Medicine as described in the OECD Health Technical Papers No. 15[1] whereby firstly, indicators have to capture an important performance aspect, secondly, they have to be scientifically sound, and thirdly, they have to be potentially feasible.

In a third step the indicators were rated according to the above mentioned scheme, whereby the **importance of an indicator** can be further broken down into three dimensions:

Impact on health: What is the impact on health associated with this problem? Does the measure address areas in which there is a clear gap between the actual and potential levels of health?

Policy importance: Are policymakers and consumers concerned about this area?

Susceptibility to being influenced by the health care system: Can the health care system meaningfully address this aspect or problem? Does the health care system have an impact on the indicator independent of confounders like patient risk? Will changes in the indicator give information about the likely success or failure of policy changes?

The **scientific soundness** of each indicator can also be broken down into two dimensions:

Face validity: Does the measure make sense logically and clinically?

Content validity: Does the measure capture meaningful aspects of the quality of care?

Aim

[1] Greenfield S, Nicolucci A, Mattke S: Selecting Indicators for the Quality of Diabetes Care at the Health System Level in the OECD Countries. OECD health Technical Papers, No.15: 2004

A comprehensive discussion of the importance and scientific soundness of those indicators can be found in a paper by Fleming et al. (2001), and in materials produced by the Alliance (NDQIA, accessed 2003).

The **feasibility** of an indicator reflects the following two dimensions:

Data availability: Are comparable data to construct an indicator available on the international level?

Reporting Burden: Does the value of the information contained in an indicator outweigh the cost of data collection and reporting?

References:

- Fleming BB, Greenfield S., Engelgau MM, et al. (2001), "The Diabetes Quality Improvement Project: moving science into health policy to gain an edge on the diabetes epidemic" Diabetes Care, Vol. 24(10), pp.1815-1820.
- National diabetes quality improvement alliance (2003), Measures and supporting document. Available at: http://www.nationaldiabetesalliance.org/measures.html. Accessed August 2003.

Sources used

Health indicators

- EUDIP ✓
- ECHI ✓
- OECD ✓

Guidelines

- IDF ✓
- SIGN ✓
- Consensus on diabetic foot ✓
- New Zealand (✓)
- ADA (✓)
- Canada ✓
- German Diabetes Association ✓

Systematic literature search in:

- Cochrane database
- Medline

Additional data provided by Quality and Outcomes Framework data

data from trials, observational studies and pilot projects sponsored by the Clinical Trials Service Unit, Oxford, the MRC Clinical Epidemiology Unit; and the experience related to retinopathy (and diabetes screening) from the UK National Screening Committee.

UK BioBank (http://www.ukbiobank.ac.uk/)

Hospital episode statistics(http://www.dh.gov.uk/PublicationsAndStatistics/Statistics/fs/en)

Other health surveys[2] and patient care organisations.

[2] e.g.http://www.drfosterintelligence.co.uk/newsPublications/article.asp?articleid=18

3. Data Items for Thematic Areas

3.1 Risk profile for Diabetes

3.1.1 Obesity & Overweight

Parameter

Overweight (BMI > 25)

Obesity (BMI ≥ 30)

Waist circumference (>94cm (men) and 80cm (women) for europids and 90 and 80cm for S. Asians and Chinese, and 85cm (men) and 90 (women) for Japanese)

References

IDF:

Alberti K, Zimmet P, Shaw J. (2006) Metabolic syndrome—a new world-wide definition. A Consensus Statement from the International Diabetes Federation, Diabet. Med. 23, 469–480

EUDIP:

- 9. Ferrannini E and Camastra S (1998) Relationship between impaired glucose tolerance, non insulin dependent diabetes mellitus and obesity (1998) EJCI 28 S2: 3-7
- 19 Edelstein SL, Knowler WC, Bain RP, Andres R, Barrett-Connor EL, Dowse GK, Haffner SM, Pettitt DJ, Sorkin JD, Muller DC, Collins VR, Hamman RF (1997) Predictors of progression from impaired glucose tolerance to NIDDM: an analysis of six prospective studies. Diabetes 46: 701-710

Comment

EUDIP:

Overweight/obesity is a major risk factor for type 2 diabetes. (9). It causes insulin resistance, which will lead eventually to type 2 diabetes.

BMI ≥ 30 kg/m2 has been used (cut off point based on recent WHO recommendation).

WHO:

BMI over 25 kg/m^2 is defined as overweight, and a BMI of over 30 kg/m2 as obese.

People with a BMI below 18.5 kg/m2 tend to be underweight

(http://www.who.int/dietphysicalactivity/media/en/gsfs_obesity.pdf).

NHS diabetes core data set:

Weight: in kilograms taken without shoes >0 – 300 kg

Height: in meters measured without shoes > 0 – 2.50 m

IDF:

Waist circumference of >94cm (men) and 80cm (women) for europids and 90 and 80cm for S. Asians and Chinese, and 85cm (men) and 90 (women) for Japanese.

DIABCARE/FQSD-Dataset:

Weight: Body-weight of the patient in kilogram (range: 0-300 or empty)

Size: Height of the patient in cm (range: 40-250 or empty)

BMI: The Body Mass Index is calculated on hand weight and size and is thus not entered. If the entered value is >40, a plausibility warning is shown. Combinations resulting in values > 90 are not allowed.

Discussion

- BMI % >25 and > 30kg/m^2 in the general population was a EUDIP core indicator, but considered too hard to assess for BIRO (recorded only for patients with diabetes)

3.1.2 Physical inactivity

Parameter

Health-enhancing physical activity (HEPA): Half an hour a day of physical activity of moderate intensity

References

EUROHIS:

- Nosikov A and Gudex C (Eds.) (2003) Developing Common Instruments for Health Surveys, IOS Press, 2003 Chapter 6.Development of a common instrument for physical activity

EUPASS:

- European Physical Activity Surveillance System (EUPASS) FINAL REPORT TO THE EUROPEAN COMMISSION (DG SANCO F/3, HEALTH MONITORING PROGRAMME), March 2001

EUDIP:

- 22. Astrup A (2001). Healthy lifestyles in Europe: prevention of obesity and type II diabetes by diet and physical activity. Public Health Nutr.;4(2B):499-515.
- 23. Liao D, Asberry PJ, Shofer JB, Callahan H, Matthys C, Boyko EJ, Leonetti D, Kahn SE, Austin M, Newell L, Schwartz RS, Fujimoto WY. (2002) Improvement of BMI, body composition and body fat distribution with lifestyle modifications in Japanese Americans with impaired glucose tolerance. Diabetes Care 25: 1504-1511

Comment

EUDIP:

Physical inactivity as an indicator of sedentary lifestyle, contributes to the development of type 2 diabetes, partly through increased risk for obesity. (22-23)
Has not been discussed by the EUDIP group due to difficult assessment.

EUPASS (European Physical Activity Surveillance System) project tested the International Physical Activity Questionnaires (IPAQ) a questionnaire which reflects duration, intensity and frequency of HEPA.

Discussion

The IPAQ questions on physical activity from EUPASS could be used as basis for an indicator, but there is no data in the moment.

3.1.3 Nutritional habits

Parameter

Total energy/Kcal intake
Total fat/carbonhydrate/proteine intake
Saturated fat intake, increased protein intake, intake of fast acting carbohydrates

References

EUROHIS:

- Nosikov A and Gudex C (Eds.)(2003) Developing Common Instruments for Health Surveys, IOS Press, 2003 Chapter 9.Development of a common instrument for use of preventive health care

EUDIP:

- 24 Hu FB, van Dam RM, Liu S.(2001) Diet and the risk of type II diabetes: the role of types of fat and carbohydrate. Diabetologia 44: 805-817
- 25 Trichopoulou A (2001) The DAFNE databank as a simple tool for nutrition policy. DAta Food NEtworking . Public Health Nutr. 4 : 1187-1198.
- 26 Brussaard JH, Lowik MR, Steingrimsdottir L, Moller A,, Kearney J, De Henauw S, Becker W; The EFCOSUM Group. (2002) . A European food consumption survey method--conclusions and recommendations. Eur J Clin Nutr.56 : S2 : S89-94

Comment

EUDIP:

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), although the evidence for fast-acting carbohydrates is questioned by some experts of the project (Adler).
Has not been discussed further by the EUDIP group.

EUROHIS: questions on nutritional habits included

Discussion

EUROHIS contains questions to be potentially used for an indicator on nutritional habits, but there is no data to use it in the moment

3.1.4 Gestational diabetes

Parameter

See *Diagnosis and classification*

References

EUDIP:

- 27. Ko GT, Chan JC, Tsang LW, Li CY, Cockram CS (1999) Glucose intolerance and other cardiovascular risk factors in Chinese women with a history of gestational diabetes. Aust N Z J Obstet Gynaecol 39: 478- 483.
- 28. Verma A, Boney CM, Tucker R, Vohr BR (2002) Insulin resistance syndrome in women with prior history of gestational diabetes mellitus . J Endocrinol Metab 87: 3227-3235
- 29. Gestational diabetes mellitus (2002) American Diabetes Association Diabetes

Comment

EUDIP:

Gestational diabetes has been recently reported as a potential risk factor for the development of type 2 diabetes. 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)

3.2 Diagnosis and classification

3.2.1 Diagnosis of Diabetes

Parameter

Date/Year of diabetes diagnose

ADA:

Fasting plasma glucose (FPG) ≥ 7.0 mmol/l

2 h OGTT (75g) – Plasma glucose optional ≥ 11,1 mmol/l

References

- Alberti KGMM, Zimmet PZ for the WHO Consultation. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Part 1: Diagnosis and Classification of Diabetes Mellitus. Provisional Report of a WHO Consultation. Diabet Med 1998;15:539-53
- World Health Organization. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Report of a WHO Consultation. Part 1: Diagnosis and Classification of Diabetes Mellitus. Geneva; 59p., WHO/NCD/NCS/99.2

IDF:

- 1. World Health Organization. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Report of a WHO Consultation. Part 1: Diagnosis and Classification of Diabetes Mellitus. Geneva: WHO Department of Noncommunicable Disease Surveillance, 1999: 1-59. http://www.who.int
- 3. Manley SM, Meyer LC, Neil HAW, Ross IS, Turner RC, Holman RR. Complications in newly diagnosed type 2 diabetic patients and their association with different clinical and biochemical risk factors. UKPDS 6. Diabetes Res 1990; 13: 1-11.
- 5. UKPDS Group. UK Prospective Diabetes Study 30: Diabetic retinopathy at diagnosis of type 2 diabetes and associated risk factors. Arch Ophthalmol 1998; 116: 297-303.
- 14. Colagiuri S, Cull CA, Holman RR. Are lower fasting plasma glucose levels at diagnosis of type 2 diabetes associated with improved outcomes? UKPDS 61. Diabetes Care 2002; 25: 1410-17.
- 18. The Expert Committee on the diagnosis and classification of diabetes mellitus. Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care 2003; 26: 3160-67.

Comment

Diagnosis (IDF)

This may either be a confirmatory FPG (≥7.0 mmol/l, >125 mg/dl) or an OGTT. The diagnostic criteria for diabetes adopted by the WHO [1] and American Diabetes Association (ADA) [18].

3.2.2 Classification of Diabetes

Parameter

ADA:

Type 1

Type 2

Gestational diabetes

Other

References

WHO:

- WHO, Laboratory Diagnosis and Monitoring of Diabetes mellitus, 2002 http://whqlibdoc.who.int/hq/2002/9241590483.pdf
- Tayside regional diabetes handbook: http://www.diabetes-healthnet.ac.uk/handbook/diagnosis.htm

Comment

Partner feedback: Graham Leese, Sven Skeie: IGT and IFG are not strictly diabetes, but reflect a pre-diabetes state. MODY are relatively small numbers. Would be interesting to look at, but many are unrecognised, and therefore the accuracy of information be poor. Reliable data will be lacking. The same for LADA (Latent autoimmune diabetes mellitus in adults).

Classification by the WHO:

Type 1 diabetes mellitus
Immune mediated
Idiopathic
Type 2 diabetes mellitus
Other specific types of diabetes
Genetic defects of islet ß-cell function
Genetic defects of insulin action
Diseases of the exocrine pancreas
Endocrinopathies
Drug- or chemical- induced diabetes
Infections
Uncommon forms of diabetes
Other genetic syndromes
Gestational diabetes mellitus

Source: WHO Laboratory Diagnosis and Monitoring of Diabetes mellitus, 2002

NHS gives an alternative approach:

NHS data set:

1. Type 1 Diabetes Mellitus

   Literature: Department of Noncommunicable Disease Surveillance. Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications. Geneva: WHO; 1999. Available from URL http://whqlibdoc.who.int/1999/who_ncd_ncs_99.2.pdf. The SDCD previously recommended codes C108. & C109., which required the additional use of the Term Code '12' to identify the appropriate synonymous terms for types 1 & 2 DM. These have been replaced by the newly available preferred term codes for types 1 & 2 diabetes. No term code is now required. For an interim period, the old codes could be mapped to these new codes until data entry system modifications have been completed.
2. Type 2 Diabetes Mellitus
3. Impaired glucose tolerance
4. Impaired fasting glucose
5. Gestational diabetes mellitus

Literature: Diagnostic criteria differ from non-pregnant state; venous plasma glucose>5.5mmol/l fasting OR >9.0mmol/l 2 hours after 75g OGTT; SIGN 55 guideline 2001 (note this differs from current WHO diagnostic criteria from GDM).

6. Maturity onset diabetes of youth (MODY)
7. Other diabetes mellitus

DIABCARE/FQSD-Dataset:

Type 1, Type 2, other

3.2.3 Diabetes onset

Parameter

Type 1 diabetes in children (0-14 years of age)

Age at diagnosis

References

- Green A, Gale EAM, Patterson CC, the EURODIAB Subarea A Study Group (1992) Incidence of childhood onset insulin dependent diabetes: The EURODIAB ACE study. Lancet 339: 905-909
- Levy-Marchal C, Patterson CC, Green A, on behalf of the EURODIAB ACE Study Group (1995) Variation in age distribution and seasonality at diagnosis of childhood IDDM in Europe. Diabetologia 38: 823-830

Comments

EUDIP Indicator on diabetes in children (0-14 years):

- Annual Incidence of Type 1 Diabetes in children between 0-14 years of age at diagnosis (clinical) 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).

EUDIP on age at onset

Age at onset plays an important role since duration of diabetes influences the risk for chronic complications (see: 51. De Lissovoy G, Ganoczy DA, Ray NF (2000), Relationship of hemoglobin A1c, age of diabetes diagnosis, and ethnicity to clinical outcomes and medical costs in a computer simulated cohort of persons with type 2 diabetes. Am J Manag Care 6, 573 – 584). Diagnosis of type 2 diabetes is not always straightforward and the level of identified diagnosis might depend on national screening programmes.

3.3 Risk profile for complications and intermediate outcomes

3.3.1 Glucose level

Parameter

HbA1c

For insulin treated diabetes observe HbA1c together with hypoglycaemic events

References

- de Boer IH, Kestenbaum B, Rue TC, Steffes MW, Cleary PA, Molitch ME, Lachin JM,Weiss NS, Brunzell JD, for the Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Study Research Group, Insulin Therapy, Hyperglycemia, and Hypertension in Type 1 Diabetes Mellitus, Arch Intern Med. 2008;168:1867-1873.
- Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA 10-Year Follow-up of Intensive Glucose Control in Type 2 Diabetes N Engl J Med. Published online 2008 Sep 10
- The ACCORD Study Group. Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial: design and methods. Am J Cardiol 2007;99(Suppl):21i–33.
- Gerstein HC, Riddle MC, Kendall DM, et al. Glycemia treatment strategies in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial. Am J Cardiol 2007;99(Suppl):34i–43.
- National Heart, Lung and Blood Institute, Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial, February 6, 2008. Available at www.nhlbi.nih.gov/ health/prof/heart/other/accord/index.htm [Accessed March 2008].
- The Action to Control Cardiovascular Risk in Diabetes Study Group, Gerstein HC, Miller ME, et al. Effects of intensive glucose lowering in type 2 diabetes. New Engl J Med 2008;358:2545–59.
- ADVANCE Collaborative Group, Patel A, MacMahon S, et al. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. New Engl J Med 2008;358:2560–72.
- Duckworth W, Abraira C, Moritz T, et al., on behalf of the VADT Investigators. Glucose control and vascular complications in veterans with type 2 diabetes. N Engl J Med 2009;360:129-39.
- Abraira C, Colwell J, Nuttall F, et al. Cardiovascular events and correlates in the Veterans Affairs Diabates Feasiility Trial: Veterans Affairs Cooperative Study Group on Glycemic Control and Complications in Type II Diabetes. Arch Intern Med 1997;157:181-8

- The University Group Diabetes Program. Effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes. VIII: Evaluation of insulin therapy: final report. Diabetes 1982;31(Suppl. 5):1-26
- UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). Lancet 1998;352:854-65
- Ohkubo Y, Kishikawa H, Araki E, Miyata T, Isami S, Motoyoshi S et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomised prospective 6-years study. Diabetes Research and Clin Pract 1995;28:103-117
- Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, Hadden D, Turner RC, Holman RR. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ. 2000; 321: 405-12

EUDIP:

- 36. Diabetes Control and Complications Trial Research Group (1993). The effect of intensive treatment on diabetes on the development and progression of long term complications in type 1 diabetes mellitus N Engl J Med 329 : 977-986
- 37. UK prospective Diabetes Study Group 33 (1998). Intensive blood glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998:352: 837-853

DMP Germany:

- Mühlhauser, I., Overmann, H., Bender R, et al. Predictors of mortality and end stage diabetic complications in patients with type 1 diabetes mellitus on intensified insulin therapy, Daibet Med 2000, 17: 727 – 34.

IDF:

- Welschen LMC, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WAB, et al. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. Diabetes Care 2005; 28: 1510-17.

DCCT/EDIC:

- Sibley SD, Thomas W, de Boer I, Brunzell JD, Steffes MW. Gender and elevated albumin excretion in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) cohort: role of central obesity. Am J Kidney Dis. 2006 Feb;47(2):223-32.
- Jenkins AJ, Lyons TJ, Zheng D, Otvos JD, Lackland DT, McGee D, Garvey WT, Klein RL; DCCT/EDIC Research Group. Lipoproteins in the DCCT/EDIC cohort: associations with diabetic nephropathy. Kidney Int. 2003 Sep;64(3):817-28.
- Alicia J. Jenkins, Timothy J. Lyons, Deyi Zheng, James D. Otvos, Daniel T. Lackland, Daniel McGee, W. Timothy Garvey, MD, Richard L. Klein and The DCCT/EDIC Research

Group: Serum Lipoproteins in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Intervention and Complications Cohort.Associations with gender and glycemia. Diabetes Care 26:810-818, 2003

- Catherine L. Martin, James Albers, William H. Herman, Patricia Cleary, Barbara Waberski, Douglas A. Greene, Martin J. Stevens, and Eva L. Feldman. Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Intervention and Complications (EDIC) Research Group. Neuropathy Among the Diabetes Control and Complications Trial Cohort 8 Years After Trial Completion. Diabetes Care 29:340-344, 2006
- Michael W. Steffes, Shalamar Sibley, Melissa Jackson, and William Thomas. ß-Cell Function and the Development of Diabetes-Related Complications in the Diabetes Control and Complications Trial Diabetes Care 26:832-836, 2003

Comment

Poor glycaemic control, obesity, lack of exercise, smoking, hyperinsulinemia, dyslipidemia and microalbuminuria are not significantly associated with stroke (Davis 1999).
Intensive glycaemic control can delay the onset and the progression of diabetic retinopathy, nephropathy and neuropathy (Ohkubo 1995).
EUDIP:
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)
SIGN 55:
Hypoglycaemic events should be assessed.
DMP Germany
Cohort study: HbA1c is the most important predictor variable for an end stage event following a diabetic nephropathy and a diabetic ulceration.
IDF:
Continuous ambulatory blood glucose monitoring has become available in recent years. There is still no good evidence-base for its use, particularly in people with Type 2 diabetes.
The meta-analysis by Welschen et al. [7] included two studies which compared self-monitoring blood glucose (SMBG) and self-monitoring of urine glucose and reported a non-significant reduction in HbA1c of 0.17 % in favour of SMBG.

3.3.2 Blood pressure

Parameters

BP systolic
BP diastolic
Method:

physician measurement

home measurement (optionally an average of several home measurements)

24 hour measurement

NHS

Year of diagnosis of hypertension: ccyy

References

- Haffner SM, Lehto S, Rönnemaa T, et al. Mortality from coronary heart disease in subjects with type 2 diabetes and in nondiabetic subjects with and without prior myocardial infarction. N Engl J Med 1998;339:229-34
- UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). Lancet 1998;352:854-65
- UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352:837-53
- UK Prospective Diabetes Study Group. Quality of Life in Type 2 Diabetic Patients is affected by Complications but not by intensive Policies to improve Blood Glucose or Blood Pressure Control (UKPDS 37). Diabetes Care 1999;22:1125-36
- UK Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. BMJ 1998;317:703-13
- Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (2003). The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. Hypertension, 2003, 42, 1206 – 1252.

EUDIP:

- 44. Joint National Committee: Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (1997). The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. Arch Intern Med 157 2413-2446
- 45. UK Prospective Diabetes Study Group 38 (1998) Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes BMJ 317 : 703-713.

Comment

The correct diagnosis of hypertension (measurement) according to international standards is a prerequisite and not further discussed here.

EUDIP:

Presence of hypertension is an independent risk factor for the development of complications. It is an established risk factor for the development of macular oedema and it is associated with proliferate retinopathy. (44-45)

According to EUDIP blood pressure should be measured with a standardised manometer, expressed in mm Hg

DIABCARE/FQSD-data set:

Blood pressure: Patient's blood-pressure in mmHg after 5 minutes rest in seated position with arm elevated/supported. (Ranges: *Systolic:* 70 - 300 or empty; *Diastolic:* 30 - 150 or empty)

Discussion:

- A value of 140/90 mmHg was consider the target blood pressure for patients with diabetes, although some guidelines state lower targets.
- In the analyses also the blood pressure distribution should be considered.
- It was suggested to record the percentage of patients with SBP >140 separately from percentage patients with DBP >90.

3.3.3 Lipids

Parameters

Total cholesterol

LDL

HDL

Total cholesterol/HDL

Triglycerides

LDL

References

- New Zealand Guidelines Group (2003) Evidence-based best practice guidelines, Review date 2006, ISBN: 0-476-00092-0.

EUDIP:

- 40. The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) (2001). Executive summary of the third report of the National Cholesterol Education Program (NCEP) expert panel on detection evaluation and treatment of high blood cholesterol in adults (adult treatment panel III) JAMA 285: 2486-2497
- 41. Pontrelli L, Parris W, Adeli K, Cheung RC (2002) Atorvastatin treatment beneficially alters the lipoprotein profile and increases low-density lipoprotein particle diameter in

patients with combined dyslipidemia and impaired fasting glucose / type 2 diabetes. Metabolism 51(3):334-42,

- 42. Sacco RL (2002) Reducing the risk of stroke in diabetes: what have we learned that is new? Diabetes Obes Metab 4 : S1;S27-34
- 43. Crespin SR (2001): What does the future hold for Diabetic dyslipidaemia? Acta Diabetol 38 : S1;S21-S26

Total cholesterol and LDL-Cholesterol:

- Vijan S, Hayward RA; American College of Physicians. Pharmacologic lipid-lowering therapy in type 2 diabetes mellitus: background paper for the American College of Physicians. Ann Intern Med. 2004;40:650-8

Comment

LDL was agreed to be problematic in practice, so the Total Chol/HDL ratio was chosen as relevant parameter.

EUDIP:

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)

Total cholesterol / HDL cholesterol (from NZ guidelines)

Target value = 4.5

High risk > 8.0

Friedemann equation

Invalid results with non-fasting triglycerides, use in diabetics has been questioned!

Reference: Wägner AM et al: Inaccuracy of Calculated LDL-Cholesterol in Type 2 Diabetes: Consequences for Patient Risk Classification and Therapeutic Decisions Clinical Chemistry 46: 1830-1832, 2000.

DIABCARE/FQSD-data set:

Fasting or non-fasting

Cholesterol: Value in mg/dl or mmol/l (Range: 10 - 2000 or empty)

HDL-Cholesterol: Value in mg/dl or mmol/l (Range: 7 - 999, or empty)

Triglyceride: Value in mg/dl or mmol/l (Range: 8 - 9999 or empty)

LDL-Cholesterol: Value in mg/dl or mmol/l (Range: 10 -400, if no value is entered and fasting=true and the other input parameters are in range, LDL is calculated using the Friedemann equation)

Triglyceride values

Triglyceride values for fasting/non-fasting are very different. Triglycerides may be used for LDL calculation only if fasting=true. Incusion is only possible together with an item for fasting status.

Discussion:

- Fasting samples are not important for most lipids, with the exception of triglycerides. In data sets it is often very difficult to know if a triglycerides recording is fasting or not. The values for fasting/non-fasting are very different. Information of Triglycerides is likely to be very inaccurate, as we will often (usually?) not know the fasting status.
- Very few patients have LDL measured directly, a calculation is used instead (Friedemann equation). Therefore for the majority of cases it will not be possible to calculate LDL cholesterol because:
  a) many patients with diabetes (esp if on insulin) find it very difficult to come to clinic fasted
  b) for the majority we shall not know if they are fasted or not
- Therefor it was agreed to stick to Total cholesterol and HDL-cholesterol measurements → Use Total cholesterol/HDL ratio instead of LDL
- Total cholesterol / HDL ratio:
  A value of 4.5 is the target value for diabetic patients
  a value >8.0 means high risk, an indicator for this threshold may be introduced later

3.3.4 Microalbuminuria (Urinary Albumin)

Parameters

Microalbumin mg/dl
Albumin excretion rate
Normoalbuminuric (AER <20 microg/min)
microalbuminuric (AER 20 –200 microg/min)
macroalbuminuric (AER >200 microg/min).
Albumin/creatinine ratio (ACR)

Microalbuminuria is defined as: • albumin:creatinine ratio >2.5mg/mmol (men) or >3.5mg/mmol (women) or albumin concentration >20mg/l.
Proteinuria is defined as: • albumin:creatinine ratio >30mg/mmol or albumin concentration >200mg/l.

References

- Jarrett RJ, Viberti GC, Argyropoulos A, Hill RD, Mahmud U, Murrells TJ: Microalbuminuria predicts mortality in non-insulin dependent diabetics, Diaet Med 1984;1:17-19;
- Mogensen CE: Microalbuminuria predicts clinical proteinuria and early mortality in maturity onset diabetes (NEJM 1984;310:356-360)
- NICE MeReC Briefing 2004;26:1-8 download from www.nice.org 05/07/06

Comment

The urinary albumin:creatinine ratio is a useful measure of renal function used in diabetic renal disease. The urinary albumin:creatinine ratio is measured using the first morning urine sample where practicable.

Microalbuminuria marker of vascular risk in diabetes (Jarrett RJ 1984; Mogensen CE, 1984)
Stages of nephropathy and glomerular filtration rate
0: normal Albuminuria
1: Microalbuminuria (30-300mg/24h urine) and normal GFR
2: Macroalbuminuria (>300mg/24h urine) and normal GFR
3: Micro- or macroalbuminuria and reduced GFR
4: ESRF
NHS data set:
Albumin excretion:
1 = Stage 1: Normoalbuminuria
Definition: For cross comparison, the value of albumin excretion by whatever method, should be graded into three stages as recommended in SIGN 55 and SIGN 11 guidelines on Management of Diabetic Renal Disease. See table in guideline for staging definitions by method. The computer program should automatically grade the stage according to the method chosen.
2 = Stage 2: Microalbuminuria
Definition: Microalbuminuria should not be diagnosed on the basis of a single urine sample result. A urinary albumin result within the microalbuminuric range (on a spot sample or timed collection) should be demonstrated on at least three separate consecutive occasions before a diagnosis of persistent microalbuminuria is made.
3. Stage 3 = Macroalbuminuria
Definition: Albuminuria should not be diagnosed on the basis of a single urine sample result. Macroalbuminuria can be diagnosed when the albustix test is positive (>= 1+) on at least three separate consecutive occasions.
DIABCARE/FQSD- data set:
Microalbumin: Value in mg/l (Range: 0 - 9999 or empty)

Other stages of renal failure:
ESRF dialysis
ESRF transplant

Suggestion: Use locally used thresholds for micro-albuminurea and qualify them as normal, micro-albuminurea and proteinurea

3.3.5 Weight

Parameters

See *Obesity*

References

- Kronsbein P, Jörgens V, Mühlhauser I, et al. Evaluation of a structured treatment and teaching programme on non-insulin-dependent diabetes. Lancet 1988;ii:1407-10

Comment

Reduction of weight leads to a reduction of HbA1c and reduced need of OAD (Kronsbein 1988)

3.3.6 Smoking

Parameters

Smoking status: never smoked, ex smoker, current smoker
Cigarettes per day
Support in smoking cessation

References

EUDIP

- 46. Haire-Joshu D, Glasgow RE, Tibbs TL (1999) Smoking and Diabetes. Diabetes Care 22 1887-1898
- 47. Mikhailidis DP, Papadakis JA, Ganotakis ES (1998) Smoking, Diabetes and hyperlipidaemia. J R Soc Health 118 :91-93

Evidence based guideline – Evidenzbasierte Leitlinie - Psychosoziales und Diabetes mellitus
*Herausgeber: Deutsche Diabetes-Gesellschaft (DDG) und Deutsches Kollegium Psychosomatische Medizin (*http://www.uni-duesseldorf.de/WWW/AWMF/ll/057-015.pdf*)*

- Will JC, Galuska DA, Ford ES, Mokdad A, Calle EE: Cigarette smoking and diabetes mellitus: evidence of a positive association from a large prospective cohort study. Int J Epidemiol 30 (3) (2001) 540-546.
- Ko GT, Chan JC, Tsang LW, Critchley JA, Cockram CS: Smoking and diabetes in Chinese men. Postgrad Med 77 (910) (2001) 551.
- Manson JE, Ajani UA, Liu S, Nathan DM, Hennekens CH: A prospective study of cigarette smoking and the incidence of diabetes mellitus among US male physicians. Am J Med 109 (7) (2000) 538-542.
- Rimm EB, Chan J, Stampfer MJ, Colditz GA, Willett WC: Prospective study of cigarette smoking, alcohol use, and the risk of diabetes in men. BMJ (England) 310 (1995) 555-559.
- Kawakami N, Takatsuka N, Shimizu H, Ishibashi H: Depressive symptoms an occurrence of type 2 diabetes among japanese men. Diabetes Care 22 (1999) 1071-1076.

- Dierkx RI, van de Hoek W, Hoekstra JB, Erkelens DW: Smoking and diabetes mellitus. Neth J Med 48 (4) (1996) 150-162.
- Beach KW, Brunzell JD, Strandness DE Jr: Prevalence of severe arteriosclerosis obliterans in patients with diabetes mellitus. Relation to smoking and form of therapy. Arteriosclerosis 2 (4) (1982) 275-280. Evidenzklasse
- Wei M, Gaskill SP, Haffner SM, Stern MP: Effects of diabetes and level of glycemia on all-cause and cardiovascular mortality. The San Antonio Heart Study. Diabetes Care 21 (1998) 1167-1172.Sawicki PT, Didjurgeit U, Mühlhauser I, Berger M: Behaviour therapy versus doctor's anti-smoking advice in diabetic patients. J Int Med 234 (4) (1993) 407-409.
- Chaturvedi N, Stephenson JM, Fuller JH: The relationship between smoking and microvascular complications in the EURODIAB IDDM complications study. Diabetes Care 18 (6) (1995) 785-792.
- Holl RW, Grabert M, Heinze E, Debatin KM: Objective assessment of smoking habits by urinary nicotinine measurement in adolescents and young adults with type 1 diabetes. Reliability of reported cigarette consumption and relationship to urinary albumin excretion. Diabetes Care 21 (1998) 787-791.
- Uchimoto S, Tsumura K, Hayashi T, Suematsu C, Endo G, Fujii S, Okada K: Impact of cigarette smoking on the incidence of type 2 diabetes mellitus in middle-aged Japanese men: the Osaka Health Survey. Diabet Med 16 (11) (1999) 951-955.
- Mehler PS, Jeffers BW, Biggerstaff SL, Schrier RW: Smoking as a risk factor for nephropathy in non-insulin-dependent diabetes. J Gen Int Med 13 (12) (1998) 842-845.
- Biesenbach G, Zazgornik J: Influence of smoking on the survival rate of diabetic patients requiring hemodialysis. Diabetes Care 19 (6) (1996) 625-628.
- Ikeda Y, Suehiro T, Takamatsu K, Yamashita H, Tamura T, Hashimoto K: Effect on the prevalence of albuminuria in Japanese men with non-insulin-dependent diabetes mellitus. Diabetes Res Clin Pract 36 (1) (1997) 57-61.
- Chase HP, Garg SK, Marshall G, Berg CL, Harris S, Jackson WE, Hamman RE: Cigarette smoking increases the risk of albuminuria among subjects with type 1 diabetes. JAMA 265 (5) (1991) 614-617.
- Biesenbach G, Zazgornik J: Influence of smoking on the survival rate of diabetic patients requiring hemodialysis. Diabetes Care 19 (6) (1996) 625-628.
- Stegmayr BG: A study of patients with diabetes mellitus (type 1) and end-stage renal failure: tobacco usage may increase risk of nephropathy and death. J Int Med 228 (2) (1990) 121-124.
- Moss SE, Klein R, Klein BE: Cigarette smoking and ten-year progression of diabetic retinopathy. Ophthalmology 103 (9) (1996) 1438-1442.

- Eadington DW, Patrick AW, Frier BM: Association between connective tissue change and smoking habit in type 2 diabetes and in non-diabetic humans. Diabetes Res Clin Pract 11 (2) (1991) 121-125.

Comment

DDG:

(Smoking increases the risk for developing type 2 diabetes (Will, 2001; Ko et al., 2001, Manson et al., 2000, Rimm, 1995, Kawakami et al., 1997))

Smoking increases the risk for cardiovascular diseases, diabetic specific neuropathy, peripheral arterial occlusive disease, erectile dysfunction, apoplexy and hypertension (Dierkx et al., 1996, Beach et al., 1982, Wei et al., 1998)

Smoking increases the risk for diabetic nephropathy (Sawicki et al., 1993, Chaturvedi et al., 1995, Holl et al., 1998, Uchimoto et al., 1999, Mehler et al., 1998, Biesenbach et al., 1997, Ikeda et al., 1997) Abstinence can meliorate an existing proteinuria (Chase et al., 1991). With renal failure smoking is an important risk factor for mortality. (Biesenbach et al., 1996, Stegmayr et al., 1990) The findings concerning diabetic retinopathy are controversial (Moss et al., 1996, Chaturvedi et al., 1995, Eadington et al., 1991)

EUDIP:

Smoking of persons with diabetes mellitus contributes to the development of cardiovascular complications. (46-47)

NHS data set:

Smoking status at date of contact:

1 = current smoker

2 = Ex smoker

3 = Never smoker

DIABCARE/FQSD-data set:

Cigarettes/ day: Number or estimates, 1 pipe equals 3 cigarettes

Discussion

Svein Skeie: Number of cigarettes per day is simple and good.

Graham Leese: In the clinics in the UK at least, clinical information is usually collected as number per day, and we have little data on how long they have been smoking for, making it difficult to calculate pack years.

3.3.7 Alcohol

Parameters

Average intake (grams/week)

Average intake (units / week) – one unit = 10g

Presence of alcohol abuse according to ICD 10, F10.2/dependence according to ICD 10 F10.3

References

Evidence based guideline – Evidenzbasierte Leitlinie - Psychosoziales und Diabetes mellitus Herausgeber: Deutsche Diabetes-Gesellschaft (DDG) und Deutsches Kollegium Psychosomatische Medizin (*http://www.uni-duesseldorf.de/WWW/AWMF/ll/057-015.pdf*)

- Lorenzo C, Serrano-Rios M, Martinez-Larrad MT, Gabriel R, Williams K, Gonzalez-Villalpando C, Stern MP, Hazuda HP, Haffner S: Prevalence of hypertension in Hispanic and non-Hispanic white populations. Hypertension 39 (2) (2002) 203-208.
- Laws A, Marcus EB, Grove JS, Curb JD: Lipids and lipoproteins as risk factors for coronary heart disease in men with abnormal glucose tolerance: the Honolulu Heart Program. J Int Med 234 (5) (1993) 471-478.
- Adler AI, Boyko EJ, Ahroni JH, Stensel, Forsberg RC, Smith DG: Risk factors for diabetic peripheral sensory neuropathy. Results of the Seattle Prospective Diabetic Foot study. Diabetes Care 20 (7) (1997) 1162-1167.
- Kästenbauer T, Sauseng S, Sokol G, Auinger M, Irsigler K: A prospective study of predictors for foot ulceration in type 2 diabetes. J AM Podiatr Med Assoc 91 (7) (2001) 343-350.
- Martin-Morales A, Sanchez-Cruz JJ, Saenz de Tejada I, Rodriguez-Vela L, Jimenez-Cruz JF, Burgos-Rodriguez R: Prevalence and independent risk factors for erectile dysfunction in Spain: results of the Epidemiologia de la Disfuncion Erectil Masculina Study. J Urol 166 (2) (2001) 569-574.
- Stepka M, Rogala H, Czyzyk A: Hypoglycemia: A major problem in the management of diabetes in the elderly. Aging 5 (2) (1993) 117-121.
- Cusi K, Consoli A: Alcoholic ketoacidosis and lactic acidosis. Diabetes Reviews 2 (2) (1994) 195-208.
- Balkau B, Eschwege E, Ducimetiere P, Richard JL, Warnet JM: The high risk of death by alcohol related diseases in subjects diagnosed as diabetic and impaired glucose tolerance: the Paris Prospective Study after 15 years of follow-up. J Clin Epidemiol 44 (6) (1991) 465-474.
- Keilman PA: Alcohol consumption and diabetes mellitus mortality in different countries. Am J Public Health 73 (11) (1983) 1316-1317.
- Lindegard B, Hillbom M: Associations between brain infarction, diabetes and alcoholism: Oberservations from the Gothenburg population cohort study. Acta Neurol Scand 75 (3) (1987) 195-200.
- The ICD-10 Classification of Mental and Behavioural Disorders World Health Organization, Geneva, 1992 F10.2 Alcohol Dependence Syndrome

Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV), published by the American Psychiatric Association, Washington D.C., 1994

Comment

Sven Skeie: Alcohol is also difficult when it comes to reliable data. The transformation table will be too complicated for daily use – can this be simplified? This might be as difficult to assess as diet and physical activity

SIGN:

High impact on micro- and macrovascular complications; should not be given up but reduced to a max. of 3 units a day

DDG:

Alcohol is a risk factor for hypertension (Lorenzo et al., 2002), hyperlipidemia (Laws et al., 1993), polyneuropathy (Adler et al., 1997) diabetic foot syndrome (Kästenbauer et al., 2001), erectile dysfunction (Martin-Morales et al., 2001), hypoglycemia and fatal cetoazidosis (Stepka et al., 1993, Cusi et al., 1994, Balkau et al., 1991, Keilman, 1983, Lindegard et al., 1987)

NHS data set:

Alcohol: Alcohol intake per average week:

Definition: Alcohol intake per average week measured in units (1 unit = 10g). Recording of a numerical value is preferred since recommended consumption limits are subject to periodic revision and may differ for pregnant women.

DIABCARE/FQSD-data set:

Alcohol: g/ Week: (conversion to gram/Week is done by physician using a conversion table with typical drinks and their alcoholic content – see below)

Amount or estimate (Range: <1000 or empty)

50g / week = occasionally

100g / week = some

200g / week = moderate

300g / week = chronic alcoholism Diagnosis preferably by ICD 10 classification

Definition Alcohol dependence*

ICD-10 Criteria for the Alcohol Dependence Syndrome

Three or more of the following manifestations should have occurred together for at least one month or, if persisting for periods of less than one month, should have occurred together repeatedly within a 12-month period:

- a strong desire or sense of compulsion to consume alcohol;
- impaired capacity to control drinking in terms of its onset, termination, or levels of use, as evidenced by:
    - alcohol being often taken in larger amounts or over a longer period than intended; or

  - by a persistent desire to or unsuccessful efforts to reduce or control alcohol use;

- a physiological withdrawal state when alcohol is reduced or ceased, as evidenced by:
  - the characteristic withdrawal syndrome for alcohol, or
  - by use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- evidence of tolerance to the effects of alcohol, such that:
  - there is a need for significantly increased amounts of alcohol to achieve intoxication or
  - the desired effect, or a markedly diminished effect with continued use of the same amount of alcohol;
- preoccupation with alcohol, as manifested by:
  - important alternative pleasures or interests being given up or reduced because of drinking; or
  - a great deal of time being spent in activities necessary to obtain, take, or recover from the effects of alcohol;
- persistent alcohol use despite clear evidence of harmful consequences, as evidenced by continued use when the individual is actually aware, or may be expected to be aware, of the nature and extent of harm.

Definition Alcohol abuse /problematic drinking

Alcohol abuse is a pattern of drinking that results in harm to one's health, interpersonal relationships or ability to work. Certain manifestations of alcohol abuse include failure to fulfill responsibilities at work, school or home; drinking in dangerous situations such as while driving; legal problems associated with alcohol use and continued drinking despite problems that are caused or worsened by drinking. Alcohol abuse can lead to alcohol dependence.

Conversion table:

Drink	**Amount**	**g Alcohol**
Schnapps	1 glass (2 cl)	7 - 8
Cognac	2 cl	7 - 8
Whiskey	2 cl	7 - 8
Liqueur	4 small glasses	20
Wine	1/4 litre	20
Wine	1/2 litre	40
Beer	2 bottles à 0.5 litre	40

3.3.8 Drug abuse/dependence

Parameter

Presence of drug abuse

Presence of drug dependence according to and ICD 10, F.11-19.2

References

- Ng RS, Darko DA, Hillson RM. Street drug use among young patients with Type 1 diabetes in the UK. Diabet Med. 2004 Mar;21(3):295-6.

Comments

Self-reported street drug usage in young adults with Type 1 diabetes is common and may contribute to poor glycaemic control and serious complications of diabetes.

ICD-10 Definition of Dependence Syndrome:

A cluster of behavioural, cognitive, and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal state. The dependence syndrome may be present for a specific psychoactive substance (e.g. tobacco, alcohol, or diazepam), for a class of substances (e.g. opioid drugs), or for a wider range of pharmacologically different psychoactive substances.

Chronic alcoholism

Dipsomania

Drug addiction

3.3.9 Foot Screening

Parameters

Former ulcer, Acute ulcer

Former Amputation above/below ankle

Foot examination: neurological examination with examination of reflex status, vibration, pain and pressure sensation (bilateral)

Palpation of foot pulse

Skin and nail status, muscle atrophy, deformations, hyperkeratosis, temperature

Control of footwear

Peripheral revascularization

References

- Spraul M, Raunest J, Reike H. Der diabetische Fuß. In Berger M: Diabetes mellitus 2000;
- SIGN (Scottish Intercollegiate Guidelines Network). Management of diabetic foot disease 2001
- Morbach S, Müller E, Reike H, Risse A, Spraul M. Diabetisches Fußsyndrom Praxis-Leitlinie, DDG, Diabetes und Stoffwechsel 13/2004, 73-76

- Morbach S, Müller E, Reike H, Risse A, Spraul M. Diagnostik, Therapie, Verlaufskontrolle und Prävention des diabetischen Fußsyndroms. Evidenzbasierte Leitlinien, Deutsche Diabetes-Gesellschaft 2004
- International Consensus on the Diabetic Foot. International Working Group on the Diabetic Foot 1999

Comment

NHS data set:

Diabetic foot risk status:

1 = low risk: SIGN 55 risk assessment criteria (adapted from Tayside Foot Risk Assessment Protocol). Low risk = Normal sensation AND good pulses, no previous ulcer, no foot deformity, normal vision.

2 = moderate risk

Moderate risk = ANY ONE of loss of sensation, absent pulses (or previous vascular surgery), significant visual impairment, physical disability (e.g. stroke, gross obesity).

3 = high risk

High risk = ANY OF previous ulcer due to neuropathy/ischaemia, absent pulses and neuropathy, Callus with risk factor (absent pulse, neuropathy, foot deformity).

4 = active foot disease

Active foot disease = Active foot ulceration, painful neuropathy which is difficult to control.

Foot pulse:

foot sensation to monofilaments

foot vibration sensation

new episode of foot ulceration

DIABCARE/FQSD data set:

Normal vibratory sensation: tuning fork examination

normal pain sensation: normal monofilament test

pulbable detectable: Aa. dorsalis pedis (dorsal pedal artery) and Aa. tib. posterior (posterior tibial artery)

peripheral Revascularisation

International Working Group on the diabetic foot (IWGDF)

Guidelines on screening uses three categories: normal/sensory neuropathy/neuropathy with ischaemia, foot deformities or previous ulcers/amputation, www.iwgdf.org/consenus

3.3.10 Eye screening

Parameters

Exam within the past 12 months

Vitrectomy

Cataract affecting eyesight

EUDIP indicators

Percent with fundus inspection in last 12m

OECD indicator

Percentage of diabetes patients who received a dilated eye examination or evaluation of retinal photography by an ophthalmologist or optometrist during the current year or during the prior year if the patient is at low risk for retinopathy

References

IDF

- 1. Scottish Intercollegiate Guidelines Network. SIGN 55. Management of Diabetes, 2001. http://www.sign.ac.uk
- 3. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Canadian Journal of Diabetes 2003; 27(Suppl 2): S76- S80. http://www.diabetes.ca
- 5. Klein R, Klein BEK, Moss SE, Davis MD, DeMets DL. The Wisconsin epidemiologic study of diabetic retinopathy III. Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years. Arch Ophthalmol 1984; 182: 527-32.
- 8. The National Collaborating Centre for Chronic Conditions. Type 1 Diabetes in Adults. National clinical guideline for diagnosis and management in primary and secondary care. http://www.rcplondon.ac.uk/pubs/books/DIA/index.asp

EUDIP

- 56. Weber B, Burger W, Hartmann R, Hovener G, Malchus R, Oberdisse U. Riskfactors for the development of retinopathy in children and adolescents with type 1 (insulin-dependent) diabetes mellitus. Diabetologia: 29: 23-29.,
- 57. American Diabetes Association (2002) Diabetic retinopathy .Diabetes Care S1.: S90-93.

Comment

SIGN 55:

Eye screening annually is highly recommended.

IDF

The importance of screening people with Type 2 diabetes at diagnosis relates to the finding that between 21 and 39 % of them already have some retinopathy (which may already be sight-threatening) by this time [3]. In the WESDR 1.6 % of people with Type 2 diabetes were legally blind [5]. For people who have no retinopathy at diagnosis of Type 2 diabetes, the chance of developing sight-threatening retinopathy within 2 years is less than 1 % [1].

Cataract is another important cause of visual loss in people with diabetes, being twice as common as in people without diabetes [1]. Recent review of screening methods found that digital photography best met the needs of appropriate sensitivity/ selectivity, feasibility and opportunities for quality assurance [8]. SIGN found that direct ophthalmoscopy only rarely achieved 80 % sensitivity even when carried out by properly trained operators [1].

Discussion

Discussion

- Modification of the OECD indicator: The time measure “within the last 12 months” is used to be more consistent with the other indicators, the restriction to ophthalmologist or optometrist was removed because of differences in different countries, and the low risk for retinopathy was removed because it is hard to assess.
- Recording modality ie ophthalmoscope, retinal photograph, slit lamp etc was considered but regarded too comlex.

3.4 Management and care of Diabetes and its comorbidities

3.4.1 Diet

Parameter

Diet (only) Y/N

References

- Kronsbein P, Jörgens V, Mühlhauser I, et al. Evaluation of a structured treatment and teaching programme on non-insulin-dependent diabetes. Lancet 1988;ii:1407-10

3.4.2 Glucose control: Oral therapy

Parameters

OAD treatment (Y/N)
Biguanides Y/N, start of treatment
Sulfonylurea Y/N, start of treatment
Glucosidase inhibitors Y/N, start of treatment
Glitazones Y/N, start of treatment
Glinides Y/N, start of treatment
OAD treatment since

References:

- The ACCORD Study Group. Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial: design and methods. Am J Cardiol 2007;99(Suppl):21i–33.

- Gerstein HC, Riddle MC, Kendall DM, et al. Glycemia treatment strategies in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial. Am J Cardiol 2007;99(Suppl):34i–43.
- National Heart, Lung and Blood Institute, Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial, February 6, 2008. Available at www.nhlbi.nih.gov/ health/prof/heart/other/accord/index.htm [Accessed March 2008].
- The Action to Control Cardiovascular Risk in Diabetes Study Group, Gerstein HC, Miller ME, et al. Effects of intensive glucose lowering in type 2 diabetes. New Engl J Med 2008;358:2545–59.
- ADVANCE Collaborative Group, Patel A, MacMahon S, et al. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. New Engl J Med 2008;358:2560–72.
- Duckworth W, Abraira C, Moritz T, et al., on behalf of the VADT Investigators. Glucose control and vascular complications in veterans with type 2 diabetes. N Engl J Med 2009;360:129-39.

Oral Therapy

- The University Group Diabetes Program. Effects of hypoglycaemic agents on vascular complications in patients with adult-onset diabetes. VIII: Evaluation of insulin therapy: final report. Diabetes 1982;31(Suppl. 5):1-26
- UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352:837-53
- UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). Lancet 1998;352:854-65
- The University Group Diabetes Program. Effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes. VIII: Evaluation of insulin therapy: final report. Diabetes 1982;31(Suppl. 5):1-26
- Leibowitz G, Cerasi E. Sulfonylurea treatment of NIDDM patients with cardiovascular disease: a mixed blessing? Diabetologia 1996;39:503-14
- Cleveland JC et al. Oral sulfonylurea hypoglycaemic agents prevent ischemic preconditioning in human myocardium. Circulation 1997;96:29-32

Comment

Many national standards recommend the following distinction:

Metformin:

For reduction of blood glucose, if BMI > 26 kg/m^2 and no contraindications for Metformin do exist.

Sulfonylurea

For reduction of blood glucose, if BMI < 26 kg/m^2 and no contraindications for Sulfonylurea do exist.

3.4.3 Glucose control: Insulin therapy

Parameters

Insulin treatment (Y/N)

Insulin treatment since

Human insulin / Insulin analogues / Animal insulin

Average number of insulin injections per day

Units per day

Pump therapy (CSII) Y/N

Long/short acting insulin

Type of insulin therapy (CIT, MDI, ODI, PIT)

References

- Ohkubo Y, Kishikawa H, Araki E, Miyata T, Isami S, Motoyoshi S et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomised prospective 6-years study. Diabetes Research and Clin Pract 1995; 28:103-117
- Staessen JA, Wang JG, Thijs L. Cardiovascular protection and blood pressure reduction: a meta-analysis. Lancet 2001;358:1305-15
- Diabetes Control and Complications Trial Research Group (1993). The effect of intensive treatment on diabetes on the development and progression of long term complications in type 1 diabetes mellitus N Engl J Med 329 : 977-986
- UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352:837-53

Comments

- Animal insulin was added to the insulin type in addition to human / analog insulin because some (few) patients still use pork insulin by preference, at least in some countries.
- No indicator for “type of insulin therapy” was introduced in the BIRO meeting in Malta because the terms (CIT, MDI, ODI, PIT) for the insulin therapy types do not cover various therapy mixes.
- The average number of insulin injections per day was considered relevant for an indicator. Computing the average doesn’t give any information on therapy types used, an analysis of distribution of insulin injections should be made.

3.4.4 Blood pressure control

Parameters

Diuretics

thiazide diuretics

spironolactone (recorded separately, since it may have treatment benefits in acute MI and congestive heart failure independent of thiazides)

β-Blockers

Ca-Antagonists

ACE inhibitors

Angiotensin Receptor Blockers (AT II Blocker)

Alpha-Blockers

Others

References

- Blood Pressure Lowering Treatment Trialists' Collaboration (BPLTTC). Effects of ACE inhibitors, calcium antagonists, and other blood-pressure-lowering drugs: results of prospectively designed overviews of randomised trials. Lancet 2000;356:1955-64
- Staessen JA, Wang JG, Thijs L. Cardiovascular protection and blood pressure reduction: a meta-analysis. Lancet 2001;358:1305-15
- Psaty BM, Smith NL, Siscovick DS, et al. Health outcomes associated with antihypertensive therapies used as first-line agents. A systematic review and meta-analysis. JAMA 1997;277:739-45
- Curb JD, Pressel SL, Cutler JA, et al. Effect of diuretic-based antihypertensive treatment on cardiovascular disease risk in older patients with isolated systolic hypertension. JAMA 1996;276:1886-92
- Borhani NO, Mercuri M, Borhani PA, et al. Final outcome results of the multicenter isradipine diuretic atherosclerosis study (MIDAS). A randomised controlled trial. JAMA 1996;276:785-91
- The ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. Major cardiovascular events in hypertensive patients randomized to Doxazosin vs Chlorthalidone. The Antihypertensive and lipid-lowering treatment to prevent heart attack trial (ALLHAT). JAMA 2000;283:1967-75
- Freemantle N; Cleland J, Young P, Mason J, Harrison J. β Blockade after myocardial infarction: systematic review and meta regression analysis. BMJ 1999;318:1730-7
- Kjekshus J, Glipin E, Cali G, Blackey, Henning H, Ross J. Diabetic patients and betablockers after acute myocardial infarction. Eur Heart J 1990;11:43-50
- Mangano DT, Layug EL, Wallace A, Tateo I,. Effect of atenolol on mortality and cardiovascular morbidity after noncardiac surgery. N Engl J Med 1996;335:1713-20

- Casas JP, Chua W, Loukogeorgakis S et al; Effect of inhibitors of the renin-angiotensin system and other antihypertensive drugs on renal outcomes: systematic review and meta-analysis, Lancet 2005; 366:2026-33.
- Lindholm LH, Ibsen H, Dahlöf B, Devereux RB, Beevers G, de Faire U, Fyhrquist F, Julius S, Kjeldsen SE, Kristiansson K, Lederballe-Pedersen O, Nieminen MS, Omvik P, Oparil S, Wedel H, Aurup P, Edelman J, Snapinn S, for the LIFE study group. Cardiovascular morbidity and mortality in patients with diabetes in the Losartan intervention for endpoint reduction in hypertension study (LIFE): a randomised trial against atenolol. Lancet 2002;359:1004-10
- Dahlöf B, Devereux RB, Kjeldsen SE, Julius S, Beevers G, de Faire U, Fyhrquist F, Ibsen H, Kristiansson K, Lederballe-Pedersen O, Lindholm LH, Nieminen MS, Omvik P, Oparil S, Wedel H, for the LIFE Study group. Cardiovascular morbidity and mortality in the losartan intervention for endpoint reduction in hypertension study. Lancet 2002;359:995-1003
- ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial. Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs. diuretic: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). JAMA. 2002 Dec 18;288(23):2981-97. Erratum in: JAMA 2003 Jan 8;289(2):178. JAMA. 2004 May 12;291(18):2196
- Staesson JA, for the Systolic Hypertension in Europe Trial Investigators. Predicting cardiovascular risk using conventional vs. ambulatory blood pressure in older patients with systolic hypertension, JAMA 1999;282:539-46
- European Society of Hypertension – European Society of Cardiology Guidelines for the management of arterial hypertension. J Hypertens 2003; 21:1011-53

3.4.5 Lipid lowering therapy

Parameters

Statins (Simvastatin, Pravastatin, Atorvastatin…)
Gemfibrizol and other fibrates
Ezetimibe (suggested by Graham Leese)
Nicotinic acid derivates (suggested by Graham Leese)
Fish oil supplementation in hypertriglyceridia (suggested by Amanda Adler)

References

- Heart Protection Study Collaborative Group. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002;360:7-22

- Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group. N Engl J Med. 1998; 339:1349-57
- Vijan S, Hayward RA; American College of Physicians. Pharmacologic lipid-lowering therapy in type 2 diabetes mellitus: background paper for the American College of Physicians. Ann Intern Med. 2004;40:650-8
- Sacks FM, Pfeffer MA, Moye LA, Rouleau JL, Rutherford JD, Cole TG, Brown L, Warnica JW, Arnold JM, Wun CC, Davis BR, Braunwald E. The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels. Cholesterol and Recurrent Events (Care) Trial investigators. N Engl J Med. 1996;335:1001-9
- Pyorala K, Pedersen TR, Kjekshus J, Faergeman O, Olsson AG, Thorgeirsson G. Cholesterol lowering with simvastatin improves prognosis of diabetic patients with coronary heart disease. A subgroup analysis of the Scandinavian Simvastatin Survival Study (4S). Diabetes Care 1997;20:614-20
- Pyorala K, Ballantyne CM, Gumbiner B, Lee MW, Shah A, Davies MJ, Mitchel YB, Pedersen TR, Kjekshus J; Scandinavian Simvastatin Survival Study (4S). Reduction of cardiovascular events by simvastatin in nondiabetic coronary heart disease patients with and without the metabolic syndrome: subgroup analyses of the Scandinavian Simvastatin Survival Study (4S). Diabetes Care. 2004 Jul;27(7):1735-40.
- Colhoun HM, Betteridge J, Durrington PN, Hitman GA, Neil, Livingstone SJ, Thomason MJ, Mackness MI, Fuller FJ. The collaborative atorvastatin diabetes study (CARDS). Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. Lancet 2004;364: 685-96

Comment

Simvastatin, Pravastatin

Secondary prophylaxis in patients with coronary heart disease, cerebrovascular disease and PVD. Primary prevention in high-risk patients.

3.4.6 Treatment of Cardiovascular disease (CVD) & peripheral vascular disease (PVD)

Parameters

Coronary revascularization:

- PTCA (Percutaneous transluminal coronary angioplasty) with/without stent
- CABG (Coronary Artery Bypass Surgery)
- anti-platelet therapy

Peripheral revascularisation:

- PTA with/without stent
- Bypass
- anti-platelet therapy

References

SIGN 32

Coronary revascularization

SIGN 55

Thrombolytic therapy

Comment

Anti-platelet therapy summarizes aspirin, platelet aggregation inhibitors, heparin as well as thrombolysis.

3.5 Self management and lifestyle management

3.5.1 Self monitoring and life style interventions

Parameter

Blood glucose (Y/N, controls/week)

Blood pressure home measurement (Y/N, controls/week)

Glucosuria self measurement (Y/N, controls/week)

Personal insulin dose adjustment

Life style interventions: see diet, exercise and education

References

- SIGN 55
- Fahey, T; Schroeder, K; Ebrahim, S(Cochrane Hypertension Group). Interventions used to improve control of blood pressure in patients with hypertension. The Cochrane Database of Systematic Reviews. The Cochrane Collaboration Volume (2), 2006, [no page #]. Date of Most Recent Update: 22-February-2006 Updated

IDF self monitoring:

- 1. McIntosh A, Hutchinson A, Home PD, Brown F, Bruce A, Damerell A, et al. Clinical guidelines and evidence review for Type 2 diabetes: management of blood glucose. Sheffi eld: ScHARR, University of Sheffi eld, 2001. http://www.nice.org.uk/pdf/NICE_full_blood_glucose.pdf
- 2. The National Collaborating Centre for Chronic Conditions. Type 1 Diabetes in Adults. National clinical guideline for diagnosis and management in primary and secondary care. http://www.rcplondon.ac.uk/pubs/ books/DIA/index.asp

- 3. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Canadian Journal of Diabetes 2003; 27(Suppl 2): S18- S23. http://www.diabetes.ca
- 4. Coster S, Gulliford MC, Seed PT, Powrie JK, Swaminathan R. Self-monitoring in Type 2 diabetes: a meta-analysis. Diabet Med 2000; 17: 755-61.
- 5. Karter AJ, Ackerson LM, Darbinian JA, D'Agostino Jr RB, Ferrara A, Liu J, et al. Self-monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente Diabetes Registry. Am J Med 2001; 111: 1-9.
- 7. Welschen LMC, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WAB, et al. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin: a systematic review. Diabetes Care 2005;28: 1510-17.

IDF life style management:

- 1. Pastors JG, Warshaw H, Daly A, Franz M, Kulkarni K. The evidence for the effectiveness of medical nutrition therapy in diabetes management. Diabetes Care 2002; 25: 608-13.
- 2. Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C. Physical activity/exercise and type 2 diabetes. Diabetes Care 2004; 27: 2518-39.
- 3. Herman WH, Hoerger TJ, Brandles M, Hicks K, Sorensen S, Zhang P, et al. Diabetes Prevention Program Research Group. The cost-effectiveness of lifestyle modifi cation or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. Ann Intern Med 2005; 142: 323-32.
- 4. The Diabetes Prevention Program Research Group. Impact of intensive lifestyle and metformin therapy on cardiovascular disease risk factors in the Diabetes Prevention Program. Diabetes Care 2005; 28: 888-94.
- 5. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care 2005; 28 (Suppl 1): S4-S36.
- 6. Franz MJ, Bantle JP, Beebe CA, Brunzell JD, Chiasson JL, Garg A, et al. Evidence-based nutrition principles and recommendations for the treatment and prevention of diabetes and related complications. Diabetes Care 2002; 25: 148-98.
- 7. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Canadian Journal of Diabetes 2003; 27(Suppl 2). http://www.diabetes.ca

Comment

SIGN 55:

Life style management

High evidence; consisting of education, frequent contacts to health care professionals, self-monitoring

Blood pressure home measurement

Pooled data from twelve RCTs on difference of mean DBP (Carnahan 1975; Soghikian 1992; Friedman 1996; Bailey 1998; Mehos 2000; Vetter 2000; Rogers 2001; Haynes 1976; Johnson 1978; Artinian 2001; Midanik 1991; Rudd 2004), showed that self-monitoring was associated with a significant reduction of -2.0 mmHg (95% CI -2.7 to -1.4 mmHg).

Self monitoring of glycaemic control

for type 1 diabetes, in type 2 no clear evidence

IDF self monitoring:

The rather unsatisfactory evidence-base surrounding selfmonitoring is addressed by guidelines from NICE [1,2] and the CDA [3]. A meta-analysis in 2000 found eight randomized trials, but no evidence for clinical effectiveness of this component of care [4]. A large observational study subsequently found evidence for improved glycaemic control with more frequent self-monitoring, regardless of therapy, but there was no stratification of new and ongoing users [5], and the NICE working group drew attention to the problem of separating out the effects of motivation in observational studies [1]. It is generally accepted that SMBG is useful in insulintreated Type 2 diabetes [1,3,5].

Also there are few data on self-monitoring using urine glucose testing. The meta-analysis by Welschen et al. [7] included two studies which compared SMBG and selfmonitoring of urine glucose and reported a non-significant reduction in HbA1c of 0.17 % in favour of SMBG.

IDF life style management

Evidence supports the effectiveness of nutrition therapy and physical activity in the prevention and management of Type 2 diabetes [1-4]. This is reflected in the current ADA standards of medical care [5] (which draw on a detailed evidence-based technical review on nutrition [6] and a more recent review on physical activity [2]) and in the Canadian guideline [7].

24 h blood pressure measurement:

Better predictor for cardiovascular mortality and morbidity in comparison to routine measurement.

3.5.2 Physical activity

Parameters

Exercise of moderate intensity

Recommendation: 30 min per day (HEPA)

→ see 3.1.2 (HEPA)

Alternative: 21min per day (DPP)

References

Canada:

- 6. Wei M, Gibbons LW, Kampert JB, et al. Low cardiorespiratory fitness and physical inactivity as predictors of mortality in men with type 2 diabetes. Ann Intern Med. 2000;132:605-611.
- 7. Hu FB, Stampfer MJ, Solomon C, et al. Physical activity and risk for cardiovascular events in diabetic women. Ann Intern Med. 2001;134:96-105.
- 8. Moy CS, Songer TJ, LaPorte RE, et al. Insulin-dependent diabetes mellitus, physical activity, and death. Am J Epidemiol. 1993;137:74-81.
- Diabetes Prevention Program (DPP) Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med, Vol. 346, No. 6 February 7, 2002

Comment

SIGN 55:

no standardized assessment

NHS data set :

Exercise physically impossible

minimal exercise

light exercise

moderate exercise

heavy exercise

Canada

Moderate to high levels of physical activity and cardio respiratory fitness are associated with substantial reductions in morbidity and mortality in both men and women and in both type 1 and type 2 diabetes. Large cohort studies have demonstrated that in people with type 2 diabetes, regular physical activity (6,7) and/or moderate to high cardiorespiratory fitness (6) were associated with reductions in cardiovascular and overall mortality of 45 to 70% over 12 to 14 years. In type 1 diabetes, a cohort study found that 7-year mortality was 50% lower in those reporting ≥2000 kcal of weekly exercise (equivalent to ≥7 hours/week of brisk walking) compared to those reporting <1000 kcal of physical activity

per week (8).

DPP recommended to engage in physical activity of moderate intensity, such as brisk walking, for at least 150 minutes per week (=21min per day)

3.5.3 Education/Empowerment

Parameters

Specific education for glucose lowering therapy

Podiatric education

Hypertension education

Inpatient/outpatient education

Structured/evaluated patient education program

Extent of patient education program (duration, units…)

Participation in health promotion programmes with relation to physical activity & weight loss

Diabetic patient organisation (membership, contact with)

Target Agreements (HbA1c, blood pressure, physical activity, diet, smoking, alcohol, …)

References

- Kronsbein P, Jörgens V, Mühlhauser I, et al. Evaluation of a structured treatment and teaching programme on non-insulin-dependent diabetes. Lancet 1988;ii:1407-10
- Trocha AK, Schmidtke C, Didjurgeit U, Muhlhauser I, Bender R, Berger M, Sawicki PT. Effects of intensified antihypertensive treatment in diabetic nephropathy: mortality and morbidity results of a prospective controlled 10-year study.
- International Consensus on the Diabetic Foot. International Working Group on the Diabetic Foot 1999
- Jaakko Tuomilehto et al: Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001; 344: 1343-1350.

IDF

- 4. NICE. Technology Appraisal 60. Guidance on the use of patient-education models for diabetes. London, National Institute for Clinical Excellence, 2003. http://www.nice.org.uk
- 5. Piette JD, Glasgow RE. Education and home glucose monitoring. In: Gerstein HC, Haynes RB (eds) Evidencebased Diabetes Care. Hamilton, Ontario: BC Decker, 2001: pp 207-51.
- 6. Gary TL, Genkinger JM, Gualler E, Peyrot M, Brancati FL. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. The Diabetes Educator 2003; 29: 488-501.
- 7. Warsi A, Wang PS, LaValley MP, Avorn J, Solomon DH. Self-management education programs in chronic disease. A systematic review and methodological critique of the literature. Arch Intern Med 2004; 164: 1641-49.

Comment

Participation in health promotion programmes with relation to physical activity & weight loss has shown to be effective in reducing the incidence of diabetes mellitus in patients with impaired fasting glucose/impaired glucose tolerance (Tuomilehto, see references above)

Reduction of weight and reduction of use of medication at same level of HbA1c

Hypertension education

The risk of end stage events could be reduced up to 70%.

Podiatric education

Neuropathy leads to the loss of perception.

IDF:

In the technology report informing its guidance on the use of patient-education models, NICE provided a review, rather than formal meta-analysis, due to differences in design, duration, outcome measures and reporting of studies [4]. NICE excluded foot self-care education but otherwise reviewed the evidence on both general and focused selfmanagement education in Type 2 diabetes. The evidence from eight trials (6 RCTs, 2 CCTs) suggested that general self-management education has a limited impact on clinical outcomes, although few long-term data were available. The evidence from eight trials (7 RCTs, 1 CCT) of focused selfmanagement education (focused on one or two aspects of self-management) suggested that this may have some effect in reducing or maintaining HbA1c levels, although there was little evidence of impact on other clinical outcomes, partly because of short study durations. Also reviewed were four trials (3 RCTs, 1 CCT) that included people with Type 1 or Type 2 diabetes, where there was some evidence that education may improve glycaemic control and quality of life, but little evidence about the longer-term benefits of education. The other reviews painted a similar picture of educational interventions producing modest improvements in glycaemic control [5-7].

3.5.4 Psychological care: Screening for depression

Parameters

WHO wellbeing 5

References

- The association of comorbid depression with mortality in patients with type 2 diabetes, Diabetes Care. 2005 Nov;28(11):2668-72
- Henkel V, Mergl R, Kohnen R, et al.Identifying depression in primary care: a comparison of different methods in a prospective cohort study. BMJ 2003;326:200
- Sharp L, Lipsky M. Screening for Depression Across the Lifespan. A Review of Measures for Use in Primary Care Settings. American Family Physician, September 15,2002/Volume 66, Number 6

IDF

- 8. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Canadian Journal of Diabetes 2003; 27(Suppl 2): S50- S52. http://www.diabetes.ca
- 9. Scottish Intercollegiate Guidelines Network. SIGN 55. Management of Diabetes, 2001. http://www.sign.ac.uk
- 10. The National Collaborating Centre for Chronic Conditions. Type 1 Diabetes in Adults. National clinical guideline for diagnosis and management in primary and secondary care. http://www.rcplondon.ac.uk/pubs/ books/DIA/index.asp
- 11. Institute for Clinical Systems Improvement (Bloomington, MN, USA). Management of Type 2 Diabetes Mellitus, 2004. http://www.icsi.org/knowledge
- 12. American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care 2005; 28 (Suppl 1): S4-S36.
- 13. Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The prevalence of comorbid depression in adults with diabetes. A meta-analysis. Diabetes Care 2001; 24:
- 1069-78.
- 14. Rubin RR, Ciechanowski P, Egede LE, Lin EHB, Lustman PJ. Recognizing and treating depression in patients with diabetes. Current Diabetes Reports 2004; 4: 119-25.
- 15. Herpertz S, Petrak F, Albus C, Hirsch A, Kruse J, Kulzer B. Psychosoziales und Diabetes mellitus. In: Deutsche Diabetes Gesellschaft (DDG) und Deutsches Kollegium Psychosomatische Medizin (DKPM) (eds) Evidenzbasierte Diabetes-Leitlinie DDG. Diabetes und Stoffwechsel 2003; 12 (Suppl 2). http://www.diabetes-psychologie.de/en/guidelines.htm
- 16. Snoek FJ, Skinner TC. Psychological counselling in problematic diabetes. Does it help? Diabet Med 2004; 19: 265-73.
- 17. Ismail K, Winkley K, Rabe-Hesketh S. Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. Lancet 2004; 363: 1589-97.

Comment

SIGN 55:

All people with diabetes should be screened for depression and offered appropriate therapy.

IDF:

Psychosocial aspects of diabetes care are included (to varying extents) in the guidelines from the CDA [8], SIGN [9], NICE (Type 1) [10] and ICSI [11] and, for the first time in 2005, in the ADA standards of care [12]. Depression has been found to be twice as prevalent in people with diabetes compared with the general population [13] and is often under-detected [14]. Evidence-based

guidelines for psychosocial care in adults with diabetes have been published under the auspices of the German Diabetes Association (DDG), indicating the level of evidence for psychological interventions in different problem areas [15]. There is growing evidence that psychological counselling can contribute to improved adherence and psychological outcomes in people with diabetes [16]. A systematic review and meta-analysis has shown that, overall, psychological interventions are effective in improving glycaemic control in
Type 2 diabetes [17].

3.5.5 Health related Quality of life

Parameters

overall and disease-specific health related quality of life Instruments:
Overall HRQoL:
EUROQOL, SF 36
Disease specific HRQoL:
The Diabetes Quality of Life Measure (DQOL) (developed in the Diabetes Control and Complications Trial, DCCT)
The Diabetes-Specific Quality of Life Scale, DSQOLS (developed in Germany)
The Diabetes Quality of Life Clinical Trial Questionnaire—Revised (DQLCTQ-R)
The Appraisal of Diabetes Scale (ADS)
The ATT-39
The Questionnaire on Stress in Patients with Diabetes—Revised (QSD-R)
The Type 2 Diabetes Symptom Checklist
The Problem Areas in Diabetes Scale (PAID-1)
The Audit of Diabetes-Dependent Quality of Life (ADDQoL)

Source:

- Redekop W, Koopmanschap M , Stolk R, Rutten G, Wolffenbuttel B, Niessen L. Health-Related Quality of Life and Treatment Satisfaction in Dutch Patients With Type 2 Diabetes. Diabetes Care 25:458-463, 2002
- Rubin R. Diabetes and Quality of Life. Diabetes Spectrum Volume 13 Number , 2000, Page 21
- Snoek F. Quality of Life: A Closer Look at Measuring Patients' Well-Being. Diabetes Spectrum Volume 13 Number , 2000, Page 24
- Delamater A. Quality of Life in Youths With Diabetes. Diabetes Spectrum
- Volume 13 Number , 2000, Page 42
- Testa M. Quality-of-Life Assessment in Diabetes Research: Interpreting the Magnitude and Meaning of Treatment Effects. Diabetes Spectrum Volume 13 Number , 2000, Page 29

- Polonsky W. Understanding and Assessing Diabetes-Specific Quality of Life. Diabetes Spectrum Volume 13 Number , 2000, Page 36
- Glasgow RE, Ruggiero L, Eakin EG, Dryfoos J, Chobanian L. Quality of life and associated characteristics in a large national sample of adults with diabetes. Diabetes Care, Vol 20, Issue 4 562-567
- AM Jacobson, M de Groot and JA Samson. The evaluation of two measures of quality of life in patients with type I and type II diabetes. Diabetes Care, Vol 17, Issue 4 267-274
- Ragnarson Tennvall G, Apelqvist J. Health-related quality of life in patients with diabetes mellitus and foot ulcers. J Diabetes Complications. 2000 Sep-Oct;14(5):235-
- Hart HE, Redekop WK, Berg M, Bilo HJ, Meyboom-de Jong B Factors that predicted change in health-related quality of life were identified in a cohort of diabetes mellitus type 1 patients. J Clin Epidemiol. 2005 Nov;58(11):1158-64. Epub 2005 Sep 12.
- Gore M, Brandenburg NA, Dukes E, Hoffman DL, Tai KS, Stacey B. Pain severity in diabetic peripheral neuropathy is associated with patient functioning, symptom levels of anxiety and depression, and sleep. J Pain Symptom Manage. 2005 Oct;30(4):374-85.
- Hart HE, Bilo HJ, Redekop WK, Stolk RP, Assink JH, Meyboom-de Jong B. Quality of life of patients with type I diabetes mellitus. Qual Life Res. 2003 Dec;12(8):1089-97.
- Bagust A, Beale S. Modelling EuroQol health-related utility values for diabetic complications from CODE-2 data. Health Economics Volume 14, Issue 3 , Pages 217 – 230. Published online 7 Sep 2004

Comments:

Health related Quality-of-life measures have been used to describe a condition or state of health, provide a prognosis, establish a reference norm, or signal a change in patient functioning.
Two major types to of HRQoL are to consider, overall and disease-specific. Overall HRQoL refers to the patient's sense of his own health and well-being in the broad areas of physical, psychological, and social functioning. When evaluating overall HRQoL, objective health status is of secondary concern; it is the patient's personal perspective on his own well-being that is paramount. Overall HRQoL is understood to be a multidimensional construct, involving a variety of domains that can contribute independently to HRQoL.
Disease-specific HRQoL refers solely to patients' sense of how the disease in question is compromising their well-being in the three broad areas of physical, psychological, and social functioning. Within such a conceptual framework, disease-specific HRQoL includes two major categories of potential distress: intrinsic impairment (the disease, or some aspect of the disease, is perceived as directly burdensome or intrusive) and attributional impairment (the disease is perceived as being responsible for distress in one or more of the three broad areas of functioning). Researchers remark, that at this time, there is no well-accepted measure that comprehensively evaluates the many aspects of diabetes-specific HRQoL as defined above.

Also, perceived HRQoL will not necessarily be closely tied to biomedical markers of diabetes, so it makes little sense to consider glycemic control or severity of complications as an appropriate gold standard.

The Euroquol has also been used in measuring the QoL of patients with complications, e.g. foot ulcers (Ragnarson et al, see references above). Modelling EuroQol health-related utility values for diabetic complications have also been undertaken by researchers (Bagust et al, see references above).

3.6 Complications

3.6.1 Acute Complications

Hypoglycaemia

Hypoglycaemia requiring medical attention

Hyperglycaemia/Ketoacidosis/Lactic acidosis

3.6.2 Eye complications

Parameters

Medical diagnosis:

- Retinopathy, proliferative => Necessity to laser or not?
- Retinopathy (mild, severe) non proliferative
- Maculopathy (diabetes related)
- Elevation of eye pressure
- Diabetic cataract
- Dry eye (eye complication of diabetic neuropathy motility disorder)

Functional losses:

- Severe vision loss
- Partial sightedness (percentage)
- Blindness

Procedures:

- Lasertherapy
- Photocoagulation
- Cataract operation
- VEGF-Therapy (still experimentell in countries like Austria)

Source

EUDIP:

- 56. Weber B, Burger W, Hartmann R, Hovener G, Malchus R, Oberdisse U. Riskfactors for the development of retinopathy in children and adolescents with type 1 (insulin-dependent) diabetes mellitus. Diabetologia: 29: 23-29.,
- 57. American Diabetes Association (2002) Diabetic retinopathy. Diabetes Care S1.: S90-93.

Comment

Microvascular complication

Definition of blindness??

EUDIP:

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.

Retinopathy:

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). 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 proliferative retinopathy is the outcome indicator.

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

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.

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.

EUDIP indicators

Percent patients with fundus inspection in last 12 months

Percent with proliferate retinopathy in last 12m

Percent who received laser treatment <3 months after diagnosis

Annual incidence of blindness due to diabetic retinopathy/total annual incidence of blindness

DIABCARE/FQSD data set:

Retina visible

If the retina is visible:

Clinically relevant macular oedema

Retinopathy

Mild/moderate

Extensive, not proliferative

Proliferative

Advanced eye damage (correlates to < 20% vision)

Visual acuity (in%) (0 – 120 or empty) – (not regarded relevant for diabetes)

Discussion

Sven Skeie: Laser treatment within 3 months after diagnosis might be difficult to collect
In the plenary discussion this was confirmed and the indicator was modified.
Graham Leese: Although blindness is very important, In Iceland they showed that for every blind patient with diabetes there are 4.5 patients with partial sightedness to the level where it may stop them working. Is there an option of trying to collect information on partial sightedness? The down side of this is that every country categorises this differently and there are different incentives in each country to record this information, which will result in differences in ascertainment.

3.6.3 Kidney damage/Nephropathy

Parameters

Plasma creatinine level
Glomerular filtration rate (GFR)
Renal replacement therapy (dialisys or transplantation)
Urinary albumin-creatinine ratio
Creatinine level

ESRF definition:

Creatinine over 400 μmol/l or previous renal transplant

OR GFR < 15 mL/min per 1.73 m^2

OR On dialysis or transplant

EUDIP Indicators

Percent patients with microalbuminuria in last 12 months

Percent with serum creatinine tested in last 12 months

Percent with ESRD in last 12 months

Annual incidence of dialysis and or transplantation (renal replacement therapy in patients with diabetes/1,000,000 general population

Prevalence (stock) of dialysis/transplantation (renal replacement therapy) in patients with diabetes/1,000,000 general population

GFR Classification:

Chronic kidney disease stage 1-4 (stage 1: GFR >90; stage 2: GFR 60-89; stage 3: GFR 30-59; stage 4: GFR 15-29)

Chronic kidney disease stage 5: GFR <15 = end stage renal disease (ESRD) or end stage renal failure (ESRF)

References

EUDIP:

- 58 Mogensen CE, Keane WF, Bennett PH, Jerums G, Parving HH, Passa P, Steffes MW, Striker GE, Viberti GC (1995) Prevention of diabetic renal disease with special reference to microalbuminuria. Lancet 346: 1080-1084

NICE:

- Clinical Guideline F- Management of type 2 diabetes. Renal disease – prevention and early management. Issue date: February 2002. Review date: March 2005 download from www.nice.org 05/07/06
- Bruno G et al. Progression to overt nephropathy in type 2 diabetes: the Casale Monferrato Study. Diabetes Care. 2003 Jul;26(7):2150-5.
- Levey A, Coresh J et al. National Kidney Foundation Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification. Annals of Internal Medicine, Volume 139, Number 2, 15 July 2003.

SIGN:

- Taal M.W & Tomson C: Clinical Practice Guidelines for the Care of Patients with Chronic Kidney Disease. UK Renal Association Clinical Practice Guidelines 4th Edition 2007
- Stages of chronic kidney disease according to the US K/DOQI-Classification
- Kidney Disease Quality Outcomes Initiative. Clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis 2002;39(2 Suppl 1) S1-S266.

Comments

NICE

Both micro- and macroalbuminuria are stronger predictors of cardiovascular mortality than of end-stage renal failure. Only a minority of patients with microalbuminuria will progress to end-stage renal failure, because death from a cardiovascular cause commonly occurs before renal failure has developed. Control of blood pressure in patients with type 2 diabetes significantly reduces the progression of diabetic kidney disease.

EUDIP:

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).

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

ESRF is defined by the WHO as serum creatinine level ≥400 µmol/l and means that dialysis is immanent. DiabCare provides information on this indicator.

NICE recommendations:

A review of longitudinal studies has shown microalbuminuria to be predictive of total mortality, cardiovascular mortality and cardiovascular morbidity.

- renal care for all people with type II diabetes
    - arrange recall and annual review for people with type II diabetes
    - review complications and risk factors at diagnosis and at least annually thereafter
    - measure urinary albumin:creatinine ratio or albumin concentration annually
        - use a first morning sample of urine where practicable
        - use a laboratory or near-patient test specifically for microalbuminuria
    - if microalbuminuria or proteinuria is present, repeat twice more (within one month where possible)
    - measure serum creatinine annually
    - classify albumin excretion annually as:
        - lower risk (absence of microalbuminuria or proteinuria), or
        - higher risk (microalbuminuria - albumin/creatinine ratio >= 2.5mg/mmol (men) or 3.5 mg/mmol (women), or albumin concentration >= 20mg/l and/or albumin/creatinine ratio greater than or equal to 30mg/mmol or albumin concentration >= 200mg/l)
- if lower-risk albumin excretion then:
    - maintain good glucose control (HbA1C below 6.5-7.5% according to the individual's target) and maintain good blood pressure control (target blood pressure <= 140/80 mmHg)
- if higher-risk albumin excretion then:
    - if retinopathy is not present then look for a non-diabetes cause of renal disease
    - ensure good glucose control as above
    - measure, assess and manged cardiovascular risk factors aggressively
    - target blood pressure <= 135/75 mmHg
    - initiate ACE inhibitor therapy for cardiovascular/renal protection

- ACE inhibitors are the drug of first choice. To achieve target blood pressure then use combination therapy if ACE inhibition alone is not fully effective
- measure urine albumin and creatinine levels at each visit
- refer for specialist/nephrological opinion if serum creatine > 150 micromol/l

ADA:

Chronic kidney disease is defined as either kidney damage or decreased kidney function (decreased glomerular filtration rate (GFR)) for 3 or more months (level A recommendation).
Persistent proteinuria is the principal marker of kidney damage. An albumin-creatinine ratio greater than 30 mg/g in untimed (spot) urine samples is usually considered abnormal; proposed sex-specific cut points are greater than 17 mg/g in men and greater than 25 mg/g in women.
Level of GFR varies according to age, sex, and body size. Normal GFR in young adults is approximately 120 to 130 mL/min per 1.73 m^2 and declines with age.
The guidelines define kidney failure as either
1) GFR less than 15 mL/min per 1.73 m^2, which is accompanied in most cases by signs and symptoms of uremia, or
2) a need to start kidney replacement therapy (dialysis or transplantation).

3.6.4 Foot complications

Parameters

Acute ulcer/amputation (above below ankle)
Infection: Wagner classification/ San Antonio Wound classification
Foot deformities, Charcot
Regular visits at diabetic foot clinic
Non-surgical therapy received on foot disease
Number of patients admitted to hospital with foot related problems (Suggestion Dundee)
Healed ulcer
Acute ulcer

EUDIP indicators

Annual incidence and/or prevalence of non-traumatic (medical) amputations, above the ankle in persons with diabetes per 100.000 general population

References

- Spraul M, Raunest J, Reike H. Der diabetische Fuß. In Berger M: Diabetes mellitus 2000
- SIGN (Scottish Intercollegiate Guidelines Network). Management of diabetic foot disease 2001
- S Morbach, E Müller, H Reike, A Risse, M Spraul. Diabetisches Fußsyndrom Praxis-Leitlinie, DDG, Diabetes und Stoffwechsel 13/2004, 73-76 (b)

- International Consensus on the Diabetic Foot. International Working Group on the Diabetic Foot 1999

SIGN 55:

- 343 Steed DL, Ricotta JJ, Prendergast JJ, Kaplan RJ, Webster MW, McGill JB, et al. Promotion and acceleration of diabetic ulcer healing by arginine-glycine-aspartic acid (RGD) peptide matrix. RGD Study Group. Diabetes Care 1995; 18: 39-46.
- 344 Holloway G,Steed D,DeMarco M,Masmuto T,Moosa H,Webster M,Bunt T,Polansky M. A randomised controlled dose response trial of activated platelet supernatant,topical CT-102 in chronic,non-healing diabetic wounds. Wounds 1993;5:198-206.
- 345 Wieman TJ, Smiell JM, Su Y. Efficacy and safety of a topical gel formulation of recombinant human platelet-derived growth factor-BB (becaplermin) in patients with chronic neuropathic diabetic ulcers. A phase III randomized placebocontrolled double-blind study. Diabetes Care 1998; 21: 822-7.
- 346 Grayson ML, Gibbons GW, Habershaw GM, Freeman DV, Pomposelli FB, Rosenblum BI, et al. Use of ampicillin/sulbactam versus imipenem/cilastatin in the treatment of limb-threatening foot infections in diabetic patients. Clin Infect Dis 1994; 18: 683-93.
- 347 Lipsky BA, Baker PD, Landon GC, Fernau R. Antibiotic therapy for diabetic foot infections: comparison of two parenteral-to-oral regimens. Clin Infect Dis 1997; 24: 643-8.
- 348 Erstad BL Jr, McIntyre KE Jr, Mills JL. Prospective, randomized comparison of ampicillin/sulbactam and cefoxitin for diabetic foot infections. Vascular Surgery 1997; 31: 419-26.
- 349 Chantelau E, Tanudjaja T, Altenhofer F, Ersanli Z, Lacigova S, Metzger C. Antibiotic treatment for uncomplicated neuropathic forefoot ulcers in diabetes: a controlled trial. Diabet Med 1996; 13: 156-9.

IDF:

- Scottish Intercollegiate Guidelines Network. SIGN 55. Management of Diabetes, 2001. http://www.sign.ac.uk
- Morbach S, Müller E, Reike H, Risse A, Spraul M. Diagnostik, Therapie, Verlaufskontrolle und Prävention des diabetischen Fußsyndroms. In: Scherbaum WA, Kiess W, Landgraf R (eds) Evidenzbasierte Diabetes-Leitlinien DDG. Diabetes und Stoffwechsel 2004; 13 (Suppl 2). http://www.deutsche-diabetes-gesellschaft.de
- Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Canadian Journal of Diabetes 2003; 27(Suppl 2): S74- S75. http://www.diabetes.ca
- National Institute for Clinical Excellence. Type 2 diabetes – footcare. London: National Institute for Clinical Excellence, 2004. http://www.nice.org.uk/page.aspx?o=101518

- Institute for Clinical Systems Improvement (Bloomington, MN, USA). Management of Type 2 Diabetes Mellitus, 2004. http://www.icsi.org/knowledge
- Campbell L, Colagiuri S, O'Rourke S, Chen M, Colagiuri R. Evidence Based Guidelines for Type 2 Diabetes. Detection and Prevention of Foot Problems. Canberra: Diabetes Australia & NHMRC, 2005. http://www.diabetesaustralia.com.au
- International Working Group on the Diabetic Foot. Apelqvist J, Bakker K, Van Houtum WH, Nabuurs- Franssen MH, Shaper NC (eds) International Consensus on the Diabetic Foot. Maastricht, The Netherlands, 1999.
- Lipsky BA. A report from the international consensus on diagnosing and treating the infected diabetic foot. Diabetes Metab Res Rev 2004; 20 (Suppl 1): S68-S77.
- Eldor R, Raz I, Ben Yehuda A, Boulton AJM. New and experimental approaches to treatment of diabetic foot ulcers: a comprehensive review of emerging treatment strategies. Diabet Med 2004; 21: 1161-73.
- Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA 2005; 293: 217-28.
- Valk GD, Kriegsman DMW, Assendelft WJJ. Patient education for preventing diabetic foot ulceration. A systematic review. Endocrinol Metab Clin North Am 2002; 31: 633-58.

Comment

IDF:

Because of the potential for improvement of health and reduction of health-care costs, the evidence surrounding diabetes foot-care has been extensively and formally reviewed many times in recent years [1-10]. The output from these documents is very consistent in suggesting that formal regular review to detect people at risk, more regular review of those found to be at risk, and intensive management of those developing foot ulceration and infection can produce major returns in avoiding the health and monetary costs of amputation. Providing foot-care education for all patients, with increased intensity for those at higher risk [11], and vascular interventions where critical ischaemia is identified (or is contributing to ulceration), are also common recommendations arising from the evidence-base.

NHS data set:

Amputation, lower limb

Amputation is defined as recommended in the SIGN guideline on Management of Diabetic Foot Disease as 'removal of forefoot or part of the lower limb'. This excludes loss of toes or single metatarsals, therefore the 4th category should be excluded from analyses based on this definition. Prevalent amputation status can be derived from this field by reference to the most recent event chronologically.

1 = transfemoral

2 = transtibial

3 = forefoot

4 = digit/metatarsal

EUDIP

This definition reflects the indicator for peripheral vascular pathology. It is assumed that in most of the cases for non-traumatic amputation diabetes mellitus is the cause. Data source should be the surgical act, surgical records.

3.6.5 Neuropathy

Parameters

Neuropathy

Sensory neuropathy (numb feet etc.)

Inability to perceive the 5.07 monofilament at one or more sites on a foot is considered to represent peripheral sensory neuropathy in that foot.
Vibration sensation measured on the plantar hallux using a 128-Hz tuning fork, graded as absent if the subject reports no vibration while the examiner can still sense vibration.
Achilles tendon reflex elicited with the subject in a seated position (see references)

Measurement: screening for neuropathy using the 10-g Semmes-Weinstein monofilament or 128-Hz tuning fork with specification to the number and location of sites to be tested

Further examination:
abbreviated neurologic examination of pinprick sensation
distal muscle strength and reflexes
Referral for additional neurologic evaluation (1)

Painful sensory neuropathy

Autonomic neuropathy

Sexual dysfunction

References

- Boyko E, Ahroni J, Stensel V, Forsberg R, Davignon D & Smith D: A Prospective Study of Risk Factors for Diabetic Foot Ulcer The Seattle Diabetic Foot Study Diabetes Care 22:1036–1042, 1999
- Vascular risk factors and diabetic neuropathy; N Engl J Med. 2005 Jan 27;352(4):341-50.

IDF:

- 1. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Canadian Journal of Diabetes 2003; 27(Suppl 2): S72- S73, S81-S82. http://www.diabetes.ca
- 2. The National Collaborating Centre for Chronic Conditions. Type 1 Diabetes in Adults. National clinical guideline for diagnosis and management in primary and secondary care. http://www.rcplondon.ac.uk/pubs/books/DIA/index.asp

- 3. Haslbeck M, Luft D, Neundörfer B, Redaelli M, Stracke H, Ziegler D, et al. Diagnose, Therapie und Verlaufskontrolle der diabetischen Neuropathie. In: Scherbaum WA, Landgraf R (eds) Evidenzbasierte Diabetes-Leitlinien DDG, 2nd edn. Deutsche Diabetes-Gesellschaft 2004. http://www.deutsche-diabetes-gesellschaft.de
- 7. Dyck PJ, Kratz KM, Karnes JL, Litchy WJ, Klein R, Pach JM, et al. The prevalence by staged severity of various types of diabetic neuropathy, retinopathy, and nephropathy in a population-based cohort: The Rochester Diabetic Neuropathy Study. Neurology 1993: 43: 817-24.
- 8. Boulton AJM, Malik RA, Arezzo JC, Sosenko JM. Diabetic somatic neuropathies (Technical Review). Diabetes Care 2004; 27: 1458-86.
- 9. Vinik AI, Maser RE, Mitchell B, Freeman R. Diabetic autonomic neuropathy: a technical review. Diabetes Care 2003; 26: 1553-79.

Comment

Canadian Diabetes Association Clinical Practice Guidelines Expert Committee

Detectable sensorimotor polyneuropathy will develop within 10 years of the onset of diabetes mellitus in 40 to 50% of people with type 1 or type 2 diabetes. Although <50% of these patients have motor or sensory symptoms, the neuropathic pain associated with symptomatic disease is frequently bothersome. Foot ulceration, which depends on the degree of foot insensitivity and amputation are important and costly sequelae of diabetic neuropathy. Both somatic and autonomic neuropathy may occur and may require referral to a specialist experienced in managing the affected body system. Mononeuropathy, particularly carpal tunnel syndrome, is common in people with diabetes and can be difficult to diagnose.

Although subclinical autonomic neuropathic manifestations are common, symptomatic involvement is infrequent.The diagnosis of symptomatic autonomic neuropathy is based on exclusion of specific cardiovascular, gastrointestinal or genitourinary pathology, usually requiring assessment by a specialist in the affected system. Treatment of autonomic neuropathy is based mainly on expert opinion, but research in this field remains active (1). The incidence of neuropathy is associated with potentially modifiable cardiovascular risk factors, including a raised triglyceride level, body-mass index, smoking, and hypertension.

Peripheral polyneuropathy → Patient is considered a high-risk patient for diabetic foot complications

IDF:

There is general agreement that stabilizing glycaemic control is important in the medium and longer term, and that tricyclic drugs should be used as first-line therapy for painful neuropathy, although side-effects are common. Exclusion of non-diabetic causes of neuropathy is important because these may account for 10 % of cases of neuropathy in people with diabetes [7]. The range of tests available in clinical and research settings is detailed in two technical reviews [8,9]. Erectile dysfunction is addressed by three of the guidelines, which draw on evidence from Type 1 as well

as Type 2 diabetes [1-3]. They conclude that the condition is rarely of simple causation, that it is important to consider the possible contribution of other medications and medical conditions, but that the expensive PDE5 inhibitors are worth a trial. The evidence-base on some of the rarer aspects of autonomic neuropathy is weak, including that for gastroparesis, and cardiovascular parasympathetic autonomic neuropathy. In general, other guidelines have relied on conventional wisdom in making recommendations over the management of gastroparesis, orthostatic hypotension, bladder dysfunction, and nocturnal diarrhoea.

NHS data set:

Erectile failure:

Definition: Failure to achieve/maintain erection sufficient for penetration. Data should remain confidential to treating physician.

3.6.6 Cardiovascular disease (CVD)

Parameters

Myocardial Infarction

Former myocardial infarction

Coronary heart disease

Stroke / Apoplexy

Transient ischaemic attacks

CHD (coronary heart disease) – risk factor

EUDIP indicators

Annual incidence of stroke in patients with diabetes per 100.000 general populations

Annual Incidence of myocardial infarction in patients with diabetes per 100.000 general population

References

- The ACCORD Study Group. Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial: design and methods. Am J Cardiol 2007;99(Suppl):21i–33.
- Gerstein HC, Riddle MC, Kendall DM, et al. Glycemia treatment strategies in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial. Am J Cardiol 2007;99(Suppl):34i–43.
- National Heart, Lung and Blood Institute, Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial, February 6, 2008. Available at www.nhlbi.nih.gov/ health/prof/heart/other/accord/index.htm [Accessed March 2008].
- The Action to Control Cardiovascular Risk in Diabetes Study Group, Gerstein HC, Miller ME, et al. Effects of intensive glucose lowering in type 2 diabetes. New Engl J Med 2008;358:2545–59.
- ADVANCE Collaborative Group, Patel A, MacMahon S, et al. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. New Engl J Med 2008;358:2560–72.
- Duckworth W, Abraira C, Moritz T, et al., on behalf of the VADT Investigators. Glucose control and vascular complications in veterans with type 2 diabetes. N Engl J Med 2009;360:129-39.

DMP Germany

CVD Type 1:

- Tuomilehto, J., Borch-Johnsen, K., Molarius, A., et al. Incidence of cardiovadcular disease in type 1 (insulin dependent) diabetic subjects with and without diabetic nephropathy in Finland, Diabetologie 1998, 41: 784 – 90.
- The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive Diabetes Treatment and Cardiovascular Disease in Patients with Type 1 Diabetes. N Engl J Med 2005;353:2643-53.

Comment

EUDIP:

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)

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)

DMP Germany: CVD

2 - 4fold development of coronary heart disease than in normal population.

Tuomilehto, J. 1998: 43% of patients with type 1 diabetes and a diabetic nephropathy experience a cardiovascular event, only 7% if there is no diabetic renal disease (Nierenschädigung?)

3.6.7 Peripheral vascular disease (PVD)

Parameters

PVD: Yes/no

Stage (category) of PVD:

Fontaine		**Rutherford**		
Stage	**Clinical**	**Grade**	**Category**	**Clinical**
I	Asymptomatic	0	0	Asymptomatic
IIa	Mild claudication	I	1	Mild claudication
IIb	Moderate-severe claudication	I	2	Moderate claudication
III	Ischemic rest pain	I	3	Severe claudication
IV	Ulceration or gangrene	II	4	Ischemic rest pain
		III	5	Minor tissue loss
		IV	6	Ulceration or gangrene

Extracted from ACC/AHA 2005 practice Guidelines for the Management of Patients With Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) *Circulation* 2006;113;1474-1547

More see 3.6.4, Foot complications

References

- ACC/AHA 2005 practice Guidelines for the Management of Patients With Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) Circulation 2006;113;1474-1547

Comment

EUDIP

Peripheral vascular disease, in addition to peripheral neuropathy and duration of diabetes over 10 years increases the risk for gangrene, foot ulcers and amputation. Myocardial infarction and stroke are increased in patients with diabetes mellitus as documented in many reports.

There is a direct relationship between existence of polyneuropathy and/or PVD and the risk for foot lesions or even amputations.
Diagnosis of PVD and treatment is based on anamnesis, clinical symptoms and the respective stage (as outlined above), not on the ABI (Doppler sonography correlates in some cases well with symptoms but is misleading in very arteriosclerotic arteries according to Medical University Graz, department of vascular surgery).

3.7 Individual characteristics, health status, demographic and socio-economic factors

3.7.1 Individual characteristics and health status

Parameters

Age
Gender
Ethnicity
Age at onset
Socio-economic status:

- Employment status
- education
- white collar/blue collar worker
- income

Other Health status indicators in ECHI:

Morbidity, disease-specific
Generic health status
Composite health status measures

References

- The Framingham Heart Study, Diabetes Care 27(3):704-708, 2004

EUDIP:

- 51. De Lissovoy G, Ganoczy DA, Ray NF (2000). Relationship of hemoglobin A1c, age of diabetes diagnosis, and ethnicity to clinical outcomes and medical costs in a computersimulated cohort of persons with type 2 diabetes. Am J Manag Care 6: 573-584

Comment

Gender perspective: Health services research has shown huge differences in access, process and outcomes between men and women.
Socio-economic status should also be recorded with every indicator.

EUDIP:
The risk for chronic complications increases with diabetes duration (51).
Duration of diabetes increases the risk of CHD death independent of coexisting risk factors. The Significant Effect of Diabetes Duration on Coronary Heart Disease Mortality

3.7.2 Population and Socio-economic factors

Parameters

Population

Total population

Median age of population, percentage -15 – 15 – 65 – 65+

Rate of urbanisation (i.e. the percentage of total urban population of a country defined according to national criteria applied at the time of the last population census.

Life expectancy in years at birth (at the age of 40 etc.) & related indicators

Sick days per year and person

Hospital days per year and person (diabetes related?)

Mortality (diabetes specific and because of diabetes specific comorbidities)

Socio-economic factors

Literacy rate

Total labour force

Total employment

Total unemployment

Social deprivation (if a common measure/index can be used)

EUDIP General mortality
Annual death rate per 100,000 populations in the general population from all causes, adjusted for standard European population
EUDIP Diabetes related mortality

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.

Cardiovascular Mortality

Cardiovascular disease is the leading cause of death in New Zealand, accounting for 40% of all deaths.

References

- ECHI working group. Design for a Set of European Community Health Indicators – Final report of the ECHI Project. 1-93. 2001
- United Nations, Department of Economic and Social Affairs Population Division (eds.). World Urbanization Prospects The 2005 Revision. Executive Summary. Fact Sheets. Data Tables. New York, 2006

MONICA

Discussion

Graham Leese: Is it worth adding social deprivation to socio-economic factors? Certainly deprivation is closely related to health outcomes, but the problem is that it would be measured very differently across the countries. Ultimately it might be good to have a “pan-european” measure of deprivation like we have a European quality of life measure (euroQol).

Sven Skeie: Very hard to collect in a comparable fashion.

3.8 Health system & health care delivery

3.8.1 Health care resources & delivery of care

Parameters

Health care resources

Facilities: hospital beds total (acute care / rehabilitation)

Manpower: physicians (GPs, specialists), diabetologists, nurses, diabetes related nurses, pharmacies, ophthalmologists, dieticians, podiatrist, cast technicians

Education of personnel

Health care delivery

Inpatient care utilisation (days per hospitalisation, hospitalisation rate per 1000 inhabitants)

Outpatient care utilization (GP contacts per patient and year)

Medicine use/medical aids

Gatekeepers

Disease Management Programs (DMP)

Definition of DMP:

Disease management is a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management:

- Supports the physician or practitioner/patient relationship and plan of care;
- Emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies; and
- Evaluates clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health.

Disease management components include: *

- Population identification processes;
- Evidence-based practice guidelines;
- Collaborative practice models to include physician and support-service providers;
- Patient self-management education (may include primary prevention, behaviour modification programs, and compliance/surveillance);
- Process and outcomes measurement, evaluation, and management;
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling).

** Note: Full-service disease management programs must include all six components. Programs consisting of fewer components are disease management support services.*

Definition DMP according to Disease Management Association of America (DMAA)

Download from http://www.dmaa.org/definition.html 30/06/06

References

- ECHI working group. Design for a Set of European Community Health Indicators – Final report of the ECHI Project. 1-93. 2001

Comment

NHS data set:

Care type:

1. Primary care only
2. Hospital diabetic clinic only
3. Shared between hospital diabetic clinic and GP

Seen by defined healthcare professional at this event:

1 = GP

2 = Diabetologist

3 = Dietician

4 = Diabetes specialist nurse

6 = Ophthalmologist

7 = Optometrist

8= Retinal screening programme

9 = Podiatrist

10 = Psychologist

Discussion

- Definition of “diabetologist” is unclear, individual specialist registers in different countries will be available as data sources, but will have different definitions.
- Number of doctors who regularly take care of diabetic patients was introduced to estimate whether patients with diabetes are treated by specialized entities or rather in the community.
- Disease Management Programmes in best-case scenarios are based on scientifically proven results.

3.8.2 Health care expenditures/financing [3]

Parameters

National expenditure on health (% of GDP)

Public and private expenditure on health

Expenditure on medical services (inpatient stays, outpatient care, medical aids, pharmaceuticals)

Medical goods dispensed to outpatients

Total health expenditure by age group

Health expenditure by fund source

Data Items for Thematic Areas

[3] Match this data with OECD data available in reports such as “Health care systems in Transition Austria 2001”

- Drugs, therapeutic products, medical aids
- Dental treatment, dentures
- Hospital care
- Medical home care
- Sickness benefits
- Maternity benefits
- Medical rehabilitation
- Health protection and disease prevention (spas)
- Early detection of disease and health promotion
- Travel expenses and transport costs.

References

- ECHI working group. Design for a Set of European Community Health Indicators – Final report of the ECHI Project. 1-93. 2001.

Discussion

Graham Leese: National expenditure on health (%GDP). Although this is useful, the %GDP depends on the denominator ie the GDP itself. It may be better to measure the amount spent on health per individual of the population as well.
Joanneum: Although of general interest, all the above mentioned indictors will not show any correlations with the health status of the population, functioning of service delivery or (diabetic) care.

3.9 Data and Documentation

3.9.1 Form, Source

Parameters

Recording: electronic, paper, online

Reliability

- Bias, completeness

Source

- Documentation
- Registries
- DiabCare System
- Surveys
- Sentinel Practise Surveillance Network (SPSN)
- Accounting systems
- Insurance/Reimbursement
- Patient associations
- Death certification

References

EUDIP Group 2002

Establishing indicators monitoring diabetes mellitus and its morbidity

3.10 FQSD/Diabcare Checkup

3.10.1 Items not yet considered

The following data items were collected by DiabCare but are not considered by BIRO

- Reason for consultation
- Type of consultation (inpatient / outpatient)
- Pregnancies and pregnancy complications (St. Vincent)
- Additional treatment (hypertension, cardiac failure, ischemic heart disease, Dyslipidaemia, Neuropathy, Other)
- Number of sick days
- Number of inpatient days

4. Results

4.1 BIRO List of indicators

Indicators marked with ✓ were selected for implementation.

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
		Epidemiology	**Definition**					
1	✓	Annual Incidence of Type 1 Diabetes in children between 0-14 years of age at diagnosis (clinical) per 100,000 children	**Numerator:** Number of children between 0-14 yrs, diagnosed (clinical) within the last 12 months with type 1 diabetes mellitus **Denominator**: Total number of children between 0-14 yrs in the study region/country/100,000	Is described in the EUDIP final report and well evaluated. Clear cut-off by choosing age group 0-14 to be more likely to count type 1 diabetes.	EUDIP Core	Y	Y	Y
2		Annual incidence of Type 1 Diabetes (%)	**Numerator**: Number of persons, diagnosed yearly with type 1 diabetes mellitus **Denominator**: Total number of general population in the study region/country	It is based on the EUDIP indicator [1] enclosing all age groups. - Diagnosis more difficult in adults.		Y	Y	Y
3		Annual incidence of Type 2 Diabetes (%)	**Numerator**: Number of persons, diagnosed within the last 12 months with type 2 diabetes mellitus **Denominator**: Total number of general population in the study region/country	It is based on the EUDIP indicator [1] enclosing all patients diagnosed with type 2 diabetes. - Diagnosis (distinction type 1 and 2 diabetes) more difficult in adults.		Y	?	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
4	✓	Prevalence of diabetes mellitus per 1,000	**Numerator**: Number of persons at a given time with confirmed diabetes mellitus **Denominator**:Total number of general population in the study region/country/1,000	No distinction between type 1 and type 2 diabetes. + Often this information comes from prescription data à no diabetes type given à better feasibility	EUDIP Core	Y	Y	?
5		Prevalence of diabetes mellitus (type 1 and type 2, respectively) (%)	**Numerator**: Number of persons at a given time with confirmed diabetes mellitus type 1 and 2 **Denominator**: Total number of general population in the study region/country	This modification of indicator [4] incorporates a distinction between type 1 and type 2 diabetes. - Distinction of diabetes types not included in all data sources (prescription data, lab data…)		Y	?	Y
6		Prevalence of persons with impaired glucose tolerance	**Numerator**: Number of persons at a given time with impaired glucose tolerance **Denominator**: Total number of general population in the study region/country/1,000	- difficult to assess - out of scope for genuine diabetes registers	EUDIP second	N	?	?
7		Annual incidence of blindness due to diabetic retinopathy/total annual incidence of blindness	**Numerator**: Number of newly diagnosed blindness due to diabetic retinopathy in all diabetes patients in study region/country **Denominator**: Number of newly diagnosed blindness in general population in the study region/country	+ blindness is major diabetes outcome - requires measurement of total annual incidence of blindness and cause of blindness (due to diabetic retinopathy) -> too hard to assess for BIRO	EUDIP Core	Y	N	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
8		Percent with ESRF in last 12 months in total population	**Numerator**:Number of patients with ESRF within the last 12 months **Denominator**: Total number of general population in the study region/country	- Relevance: Relation to total population mainly interesting for epidemiology. Data on this issue is available in national registries. Reimbursement systems may offer information since both of them are coded according to the ICD.	EUDIP second	Y	Y	Y
9		Annual incidence of dialysis and/or transplantation (renal replacement therapy in patients with diabetes)/general population	**Numerator**: Number of dialysis and or transplantation (renal replacement therapy in patients with diabetes) within the last 12 months **Denominator**: Total number of patients with diabetes / general population in the study region/country/1,000,000	- Relevance: Relation to total population mainly interesting for epidemiologists. Data on this issue is available in national registries. Reimbursement systems may offer information since both of them are coded according to the ICD.	EUDIP Core	Y	Y	Y
10		Prevalence of dialysis/transplantation (renal replacement therapy) in patients with diabetes/general population	**Numerator**: Number of patients with dialysis and or transplantation (renal replacement therapy in patients with diabetes) at a given time **Denominator**: Total number of patients with diabetes / general population in the study region/country/1,000,000	- Relevance: Relation to total population mainly interesting for epidemiologists. More details see indicator [9]	EUDIP Core	?	N	Y
11		Annual incidence of non-traumatic (medical) amputations, above the ankle in persons with diabetes/general population	**Numerator**: Number of non-traumatic (medical) amputations, above the ankle in persons with diabetes new within the last 12 months **Denominator**: Total number of patients	- Relevance: Relation to total population mainly interesting for epidemiologists. Data source should be the surgical act, surgical records.	EUDIP	Y	?	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
			with diabetes / general population in the study region/country/100,000					
12		Prevalence of non-traumatic (medical) amputations, above the ankle in persons with diabetes/general population	**Numerator**: Number of non-traumatic (medical) amputations, above the ankle in persons with diabetes at a given time **Denominator**: Total number of patients with diabetes / general population in the study region/country/100,000	- Relevance: Relation to total population mainly interesting for epidemiologists. This indicator complements indicator [11].		?	N	Y
13		Annual incidence of stroke in patients with diabetes/general population	**Numerator**: Number of strokes in persons with diabetes new within the last 12 months **Denominator**: Total number of patients with diabetes / general population in the study region/country/100,000	- Relevance: Relation to total population mainly interesting for epidemiologists. Source: ICD, ?	EUDIP	Y	Y	Y
14		Prevalence of stroke in patients with diabetes/general population	**Numerator**: Number of stroke events in persons with diabetes at a given time **Denominator**: Total number of patients with diabetes / general population in the study region/country/100,000	- Relevance: Relation to total population mainly interesting for epidemiologists. This indicator supplements [13].		?	?	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
15		Annual Incidence of myocardial infarction in patients with diabetes/general population	**Numerator**: Number of myocardial infarctions in persons with diabetes new within the last 12 months **Denominator**: Total number of patients with diabetes / general population in the study region/country/100,000	- Relevance: Relation to total population mainly interesting for epidemiologists. Possibility of underestimation of MI in patients with diabetes.	EUDIP	Y	Y	Y
16		Prevalence of myocardial infarction in patients with diabetes/general population	**Numerator**: Number of myocardial infarctions in persons with diabetes at a given time **Denominator**: Total number of patients with diabetes / general population in the study region/country/100,000	- Relevance: Relation to total population mainly interesting for epidemiologists. Modification of indicator [15].		?	?	Y
17	✓	Age at diagnosis by 10 year age bands (incidence)	**Numerator**: Number of diagnosed patients within an age band **Denominator**: Population in the study region/country	Source: Patient records, DiabCare One often has to rely on information given by the patient.	EUDIP second	?	Y	Y
		Structural quality						
18	✓	Hospital beds per 100,000 population	**Numerator**: Number of hospital beds **Denominator**: Population in the study region/country/100,000	Not all categories of beds have to be collected separately, maybe just count hospital beds.	ECHI-2	?	Y	Y
19	✓	Physicians employed per 100,000 population	**Numerator**: Number of physicians employed in study region/country **Denominator**: Population in the study region/country/100,000	This indicator might be easy to assess. National statistics can provide information on this indicator.	ECHI-2	Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
20	✓	Number of diabetologists per 100,000	**Numerator**: Number of diabetologists in the study region/country **Denominator**: Population in the study region/country/100,000	Diabetologists are an important part in the process of treating patients with diabetes. Definition of a diabetologists is unclear. Comparison is difficult. Data should come from national Specialist Registers.		Y	?	Y
21	✓	Number of doctors who regularly take care of diabetic patients in diabetes clinics in primary or secondary care per 100,000	**Numerator**: Number of doctors who regularly take care of diabetic patients in diabetes clinics in primary or secondary care **Denominator**: Population in the study region/country/100,000	Definition “regularly” to be discussed	BIRO meeting Malta	Y	?	?
22		Nurses employed per 100,000	**Numerator**: Number of nurses **Denominator**: Population in the study region/country /100,000	Data available from national statistics	ECHI-2	Y	Y	Y
23	✓	Number of diabetes nurses employed per 100,000	**Numerator**: Number of diabetes specific nurses **Denominator**: Population in the study region/country /100,000	Introduced to distinguish between nurses and specialized diabetes nurses.		Y	?	Y
24	✓	Number of physicians who offer structured Disease Management Programme participations to patients per 1000 patients with diabetes mellitus	**Numerator**: Number of physicians who offer structured DMP participation to patients in the study region/country **Denominator**: Total number of diabetic patients in the study region/country / 1000	Availability of a DMP influences the level of structured and evidence based treatment.		Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
25	✓	Portion of diabetic patients enrolled in structured Disease Management Programmes (DMP)	**Numerator**: Number of diabetic patients enrolled in structured DMP in the study region/country **Denominator**: Total number of diabetic patients in the study region/country	Availability of a DMP influences the level of structured and evidence based treatment.	Joanneum, Fred Storms	Y	Y	Y
26		Health care expenses per inhabitant	**Numerator**: Health care expenses **Denominator**: Population in the study region/country	It is common use to compare health care systems by the amount of health care expenses. National statistics provide information on this indicator.		Y	Y	Y
		Process quality						
27	✓	Percentage of patients with one or more HbA1c tests during the last 12 months	**Numerator**: Number of diabetes patients within a population with one or more HbA1c tests in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	+ This indicator is one of the six suggested process indicators by the OECD. + For international comparability use the OECD definitions. + High importance and scientific soundness.	OECD + EUDIP second	Y	Y	Y
28	✓	Percentage of patients with one or more Total cholesterol/HDL tests during the last 12 months	**Numerator**: Number of diabetes patients within a population with one or more Total cholesterol/HDL tests in a given year. **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [27]. EUDIP uses “lipid profile (total chol., LDL, HDL, trigl.) measured within the last 12 months”, OECD uses LDL only, BIRO recommends Total chol./HDL chol.	OECD + EUDIP second (modified)	Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
29	✓	Percentage of patients with at least one test for microalbuminuria during the measurement year or who had evidence of medical attention for existing nephropathy	**Numerator**: Number of diabetes patients with one or more tests for microalbuminuria in a given year or attention for existing nephropathy **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [27]. Therapeutic consequences of Microalbuminuria tests are unclear.	OECD + EUDIP second	?	Y	?
30	✓	Percentage of diabetes patients who received a dilated eye examination or evaluation of retinal photography by a trained caregiver within the last 12 months	**Numerator**: Number of diabetes patients with dilated eye examination or evaluation of retinal photography **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [27]. The OECD indicator was modified, see discussion in indicator description.	OECD, modified by BIRO group	Y	Y	Y
31	✓	Percentage of diabetes patients receiving at least one foot examination within the last 12 months	**Numerator**: Number of diabetes patients receiving at least one foot examination annually **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [27].	OECD	Y	Y	Y
32	✓	Percentage of diabetes patients whose smoking status was ascertained and documented within the last 12 months	**Numerator**: Number of diabetes patients with smoking status documentation in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [27].	OECD	?	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
33		Percentage of patients whose alcohol use was ascertained and documented within the last 12 months	**Numerator**: Number of diabetes patients with alcohol use documentation in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	This indicator displays the above-mentioned indicator [32] modified for alcohol use.		?	Y	?
34	✓	Percent with serum creatinine tested in last 12 months	**Numerator**: Number of diabetes patients with serum creatinine tests in last 12 months **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country		EUDIP second	Y	Y	Y
35	✓	Percentage of patients with diabetes and one or more blood pressure measurements within the last 12 months	**Numerator**: Number of diabetes patients with one or more blood pressure measurements in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Blood pressure control is clinically important	EUDIP second	Y	Y	Y
36	✓	Percentage of diabetes patients with clinically diagnosed hypertension who receive antihypertensive medication	**Numerator**: Number of diabetes patients with clinically diagnosed hypertension who receive antihypertensive medication **Denominator**: Number of clinically diagnosed diabetes patients with hypertension in the study region/country	Hypertension is defined by either hypertension treatment or blood pressure > 140/90		Y	?	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
37		Percentage of patients with one or more depression tests annually	**Numerator**: Number of diabetes patients within a population with one or more tests for depression in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Recent guidelines emphasize the importance of screening for depression. Excluded in BIRO Meeting in Malta		Y	Y	Y
38		Percentage of patients with one or more HRQoL tests annually	**Numerator**: Number of diabetes patients within a population with one or more tests HRQoL in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country					
39	✓	Percentage of patients with diabetes specific education at least once before	**Numerator**: Number of diabetes patients within a population with one or more diabetes specific education/at least one before **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Diabetic specific education can lead to better outcome in patients with diabetes.		Y	?	Y
40		Thrombolytic therapy in diabetic patients with previous myocardial infarction	**Numerator**: Number of diabetes patients with thrombolytic therapy (i.e. vitamin K antagonists or thrombocyte aggregation inhibitors) in patients with myocardial infarction **Denominator**: Number of clinically	- Feasible?		Y	N	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
			diagnosed diabetes patients with coronary heart disease in the study region/country					
41	✓	Type of oral therapy (distribution of agents) in patients with diabetes type 2	**Numerator**: Number of diabetes patients who are treated with biguanides, sulfonuria etc. **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country who receive oral hyperglycaemic therapy	Which oral anti diabetic agents are used? Interesting for treatment processes, maybe even for research? If distribution is not feasible, change this indicator to “Portion of OAD treated patients”		?	Y	?
42	✓	Portion of patients with OAD therapy in patients with diabetes type 2	**Numerator**: Number of clinically diagnosed diabetes patients who receive oral hyperglycaemic therapy **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Relevant for type 2.		Y	Y	?
43	✓	Portion of patients treated with insulin among patients with diabetes	**Numerator**: Number of patients with diabetes receiving exclusively insulin **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Relevant for type 2.		Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
44	✓	Portion of patients treated with insulin in combination with OADs among patients with diabetes	**Numerator**: Number of patients with diabetes receiving insulin in combination with oral anti diabetic agents **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Relevant for type 2.		Y	Y	?
45		Type of insulin therapy	**Numerator**: Number of diabetes patients receiving insulin as CIT, MDI, ODI, PIT (type: long-, short-acting/mixtures) **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country who receive insulin therapy	CSII, MDI, ODI, PIT This indicator was dropped in the BIRO meeting in Malta because the names used for therapies do not cover various therapy mixes		Y	Y	Y
46	✓	Percentage of insulin treated patients with pump therapy	**Numerator**: Number of insulin treated diabetes patients with pump therapy **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country who receive insulin therapy	This indicator is a subset of indicator [45]	BIRO meeting Malta	Y	Y	Y
47	✓	Average number of insulin injections per day in insulin treated patients	**Numerator**: Sum of insulin injections in all diabetes patients with insulin therapy **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country who receive insulin therapy	This indicator was introduced in the BIRO meeting in Malta because of the problems with indicator [45] It is recommended to display this indicator as a distribution (histogram)	BIRO meeting Malta	?	Y	?
48	✓	Portion of diabetic patients treated with diet only	**Numerator**: Number of patients with diabetes receiving diet only **Denominator**: Number of clinically	Item is present in DiabCare data set + this information can not be deduced from drug prescriptions and is therefore	Suggestion Amanda Adler	Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
			diagnosed diabetes patients in the study region/country	interesting to assess seperately				
49		Type of blood pressure measurement in patients with diabetes	**Numerator**: Number of blood pressure measurements in diabetes patients with method X **Denominator**: Total number of blood pressure measurements in clinically diagnosed diabetes patients in the study region/country	EUDIP suggested the standardization of blood pressure measurement. The method might be documented in the patient's record. Eligible methods for blood pressure measurement are: physician/home measurement, 24 hour measurement. Not considered relevant in Malta BIRO meeting		N	N	Y
50		Type of blood pressure treatment / first line treatment in patients with diabetes	**Numerator**: Number of diabetes patients with hypertension separated according to type of antihypertensive medication / first line treatment **Denominator**: Number of clinically diagnosed diabetes patients with hypertension in the study region/country	Which anti hypertensive agents are used? Interesting for treatment processes, maybe even for research? But hard to record -> not feasible		Y	N	?
51	✓	Portion of diabetes patients with anti hypertensive treatment	**Numerator**: Number of diabetes patients with anti hypertensive treatment **Denominator**: Number of clinically diagnosed diabetes patients with hypertension in the study region/country	Included in BIRO meeting in Malta	Joanneum, Fred Storms	Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
52		Average number of antihypertensive agents used per diabetes patient with anti hypertensive treatment	**Numerator**: Number of antihypertensive agents used per diabetes patient with anti-hypertensive treatment **Denominator**: Number of patients with clinically diagnosed diabetes and anti-hypertensive treatment		Bergen, Svein Skeie	Y	Y	Y
53	✓	Portion of diabetes patients with lipid lowering medication	**Numerator**: Number of diabetic patients receiving lipid lowering medication **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Important process in treatment practice	BIRO	Y	Y	Y
54	✓	Percent of patients with diabetes performing self-monitoring of blood glucose/ urine testing	**Numerator**: Number of diabetes patients performing self-monitoring of blood glucose **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Important process for patient empowerment		?	Y	Y
55		Percent of patients with hypertension performing self-monitoring of blood pressure	**Numerator**: Number of diabetes patients performing self-monitoring of blood pressure **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Important process for patient empowerment Excluded in BIRO meeting in Malta. Rediscuss this, evidence is there		Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
56	✓	Percent of patients with clinically diagnosed CVD and diabetes who are treated with anti-platelet therapy	**Numerator**: Number of patients with clinically diagnosed diabetes and CVD treated with anti-platelet therapy **Denominator**:Number of patients with clinically diagnosed diabetes and CVD in study region/country			Y	Y	Y
		Outcome quality – intermediate outcomes						
57	✓	Percentage of patients with most recent HbA1c level >9.0% (poor control)	**Numerator**: Number of diabetes patients with most recent HbA1c level >9.0% (poor control) **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Use OECD indicator definition for international comparability. + Important parameter	OECD EUDIP second	Y	Y	Y
58	✓	Percentage of patients with most recent HbA1c level >7,5%	**Numerator**: Number of diabetes patients with most recent HbA1c level >7.5% **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Modification of indicator [57] for good control, EUDIP uses threshold >7,5% introduced in BIRO meeting in Malta -> display HbA1c distribution in addition	OECD EUDIP second	Y	Y	Y
59		Percentage of patient with most recent LDL<130 mg/dl	**Numerator**: Number of diabetes patients with most recent LDL<130 mg/dl **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [57] LDL is often not measured and unreliable because calculated EUDIP specifies thresholds also for total cholesterol (>5 mmol/l), LDL (>2,6 mmol/l), HDL (<1,15 mmol/l), triglyc (>2,3 mmol/l)	OECD	?	N	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
60	✓	Percentage of patients with Total-Chol / HDL-Chol < 4.5	**Numerator**: Number of diabetes patients with most recent Total Chol / HDL Chol < 4.5 **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Selected instead of indicator [57] because LDL is problematic in practice A value of 4.5 is the target value for diabetic patients, a value >8.0 means high risk, may be introduced later	BIRO meeting Malta	Y	Y	Y
61	✓	Percentage of patients with most recent blood pressure <140/90 mmHg	**Numerator**: Number of diabetes patients with most recent blood pressure <140/90 mmHg **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [57] Some guidelines use lower threshold value – for outcome quality measurement 140/90 is appropriate. -> show distribution in addition It was also recommended to analyze percentage of patients with SBP >140 separately from percentage patients with DBP >90	OECD	Y	Y	Y
62		Percentage of patients with depression (Wellbeing 5 level below 13)	**Numerator**: Number of patients with depression (Wellbeing 5 level below 13) **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	See description indicator [37].		Y	Y	Y
63	✓	Percentage of patients with BMI ≥ 30 kg/m2	**Numerator**: Number of patients with BMI ≥ 30 kg/m2 **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Overweight and obesity are considered as a major risk factor for developing micro and macro vascular complications. Overweight is defined as BMI ≥ 25 kg/m2 Obesity is defined as BMI ≥ 30 kg/m2	EUDIP second	Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
64		Percentage of patients with waist circumference above IDF cut-offs	**Numerator**: Number of persons with diabetes mellitus with waist circumference above 94cm (men) and 80cm (women) for europids and 90 and 80cm for S. Asians and Chinese, and 85cm (men) and 90 (women) for Japanese) **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	94cm (men) and 80cm (women) for europids and 90 and 80cm for S. Asians and Chinese, and 85cm (men) and 90 (women) for Japanese) - Also recording of Ethnicity is required, which is hardly ever done - After discussion collection decided that waist circumference not adopted for core data set	Dundee, BIRO meeting Malta	Y	?	Y
65	✓	Percentage of persons with diabetes and proliferate retinopathy and/or maculopathy who had a fundus inspection in the last 12 months	**Numerator**: Number of persons with diabetes mellitus and proliferate retinopathy and/or maculopathy who had a fundus inspection in the last 12 months **Denominator**: Number of patients tested with eye inspection or fundus photography	EUDIP defines retinopathy as the presence of the growth of new blood vessels on the retina and the posterior surface of the vitreous. Reimbursement codes in some countries offer codes for laser treatment. Additionally to the ICD-Codes a validation of laser treatment is possible.	EUDIP second	Y	Y	Y
66		Percent who received laser treatment <3 months after diagnosis of proliferative retinopathy	**Numerator**: Number of diabetic patients who receive laser treatment < 3 months after diagnosis **Denominator**: Denominator: Number of clinically diagnosed diabetes patients in the study region/country	Referred to as outcome indicator by EUDIP, but isn't this rather a process indicator?? Difficult to assess! (3 months??)	EUDIP second	Y	N	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
67	✓	Percentage of patients with eye laser treatment ever	**Numerator**: Number of diabetic patients who received eye laser treatment ever **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Intermediate outcome for retinopathy Interesting to compare how health care systems deal with retinopathy		Y	Y	Y
68	✓	Percentage with microalbuminuria in last 12 months (among those who have been tested)	**Numerator**: Number of diabetes patients tested positively for urinary albumin **Denominator**: Overall number of diabetes patients with tests for urinary albumin	that gives a rate of "newly found" patients with microalbuminuria - Difficult to compare (who has been screened??)	BIRO meeting Malta			
69	✓	Rate of current smokers among diabetes patients	**Numerator**: Number of smokers among diabetes patients **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	Smoking is an important risk factor.	EUDIP second	Y	Y	Y
70	✓	Rate of patients with current alcohol abuse/dependence	**Numerator**: Number of patients with current alcohol abuse/dependency among diabetes patients **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country		BIRO meeting Malta	Y	?	Y
71		Rate of patients with current drug abuse/dependance	**Numerator**: Number of patients with current (illegal) drug abuse/dependance among diabetes patients **Denominator**: Number of clinically diagnosed diabetes patients in the study	Introduced in BIRO meeting in Malta, drug abuse in Type 1 has an influence on glycaemic control Test/discuss this parameter before area-wide recommendation		?	?	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
			region/country					
72	✓	Former or current foot ulceration	**Numerator**: Number of patients with former or acute foot ulceration **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	"Foot on Risk…"		Y	Y	Y
		Outcome Quality – Terminal outcomes						
73		Cardiovascular mortality in patients with diabetes	**Numerator**: Number of cardiovascular deaths in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	This indicator is useful to compare performance of health care systems. Data might be available by national registries or ICD - very biased data, hard to assess For classification of cardiovascular deaths see population and socio-economic factors	OECD - newly proposed measures	Y	N	Y
74	✓	Annual incidence of blindness in patients with diabetes (among those visited during the last 12 months)	**Numerator**: Number of diabetes patients recorded to have become blind **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country who visited during the last 12 months	+ Easier to assess than indicator [7] 'due to diabetic retinopathy' is hard to assess The original EUDIP indicator is 'Annual incidence of blindness due to diabetic retinopathy/total annual incidence of blindness' Discussion The BIRO group found it hard	EUDIP, modified in BIRO meeting in Malta	Y	?	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
				to record the reason for blindness				
75		Prevalence of blindness due to diabetic retinopathy in diabetic patients	**Numerator**: Number of diabetes patients who are blind due to diabetic retinopathy at a given time **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	+ Easier to assess than indicator [7] The same modification as for indicator [74] is recommended. Excluded from BIRO set of indicators because prevalence is too hard to assess.		Y	N	Y
76	✓	Annual incidence of dialysis and/or transplantation (renal replacement therapy in patients with diabetes	**Numerator**: Number of patients who newly receive dialysis and/or transplantation **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	This indicator modifies indicator [9] to be used as outcome indicator.	EUDIP (Joanneum)	Y	Y	Y
77	✓	ESRD in Persons with Diabetes	**Numerator**: Number of diabetes patients with ESRD **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	EUDIP uses two related indicator in connection with epidemiology of complications: indicator [8], indicator [10] ('Prevalence (stock) of dialysis/ transplantation (renal replacement therapy) in patients with diabetes')	OECD, (EUDIP)	Y	Y	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
78	✓	Annual incidence of amputations above the ankle	**Numerator**: Number of diabetes patients with major (above the ankle) amputations in a given year **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	EUDIP definition “amputations above the ankle” was preferred (see indicator [11]). OECD suggestion is “Lower extremity amputation rates”, major (above or below knee) amputations	EUDIP OECD	Y	?	Y
79	✓	Annual incidence of stroke in patients with diabetes	**Numerator**: Number of diabetes patients with new onset of stroke **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	This indicator modifies indicator [13] to be used as outcome indicator. - stroke and diabetes have to be known in combination	Joanneum (EUDIP)	Y	?	Y
80		Prevalence of stroke among diabetes patients	**Numerator**: Number of stroke in patients with diabetes **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	This indicator supplements indicator [79]		Y	N	Y
81	✓	Annual Incidence of myocardial infarction in patients with diabetes	**Numerator**: Number of patients with new onset of myocardial infarction **Denominator**: Number of clinically diagnosed diabetes patients in the study region/country	This indicator modifies indicator [15] to be used as outcome indicator. - stroke and diabetes have to be known in combination	Joanneum (EUDIP)	Y	?	Y
82		Prevalence of myocardial infarction in patients with diabetes	**Numerator**: Number of diabetic patients with history of stroke **Denominator**: Number of clinically diagnosed diabetes patients in the study	Supplement to indicator [81].		Y	N	Y

Nr.	BIRO Sel.			Comment	Source	Importance	Feasibility	Scientific Soundness
			region/country					
83		Annual death rate per 100,000 populations in the general population from all causes, adjusted for standard European population	**Numerator**: Annual death rate from all causes **Denominator**: General population/100,000 adjusted for standard European population		EUDIP			
84	✓	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.	**Numerator**: Annual death rate in patients who have as primary or secondary cause of death diabetes mellitus **Denominator**: General population/100,000 adjusted for standard European population	Major indicator for diabetes complications. EUDIP suggests the linkage of the death rate with gender and age. Data sources are national registries. - diabetes often is not well recorded as primary or secondary cause of death	EUDIP Core	Y	N	Y
85		Mortality attributable to diabetes mellitus	**Numerator**: Diabetes specific mortality per age group **Denominator**: General mortality per age group	- Requires diabetes specific mortality and mortality in general population per age group.		Y	?	Y

4.2 BIRO Data Set

The following list of data items is required to compute the BIRO indicators (marked with ✓)

Data item
Year of birth
Sex
Height
Epidemiology
Diabetes type
Newly diagnosed diabetes
Year of diagnosis
Total number of children between 0-14 yrs
Diabetes y/n
Total number of general population in area
Age at diagnosis
Structural quality
hospital beds in area
physicians employed in area
number of diabetologists in area
number of doctors who regularly take care of diabetic patients in diabetes clinics in primary or secondary care in area
nuber of diabetes nurses employed in area
number of physicians who offer structured Disease Management Programmes (DMP) in area
Patient enrolled in structured Disease Management Program (DMP)
Process quality
Number of clinically diagnosed diabetes patients in the area
HbA1c tested within last 12 months y/n
Total Chol/HDL tested within last 12 months y/n
Microalbuminuria tested within last 12 months y/n
Medical attention for nephropathy within last 12 months y/n
Dilated eye examination or evaluation of retinal photography by a trained caregiver within the last 12 months y/n

At least one foot examination within last 12 months y/n
Smoking status ascertained within last 12 months y/n
Serum creatinine tested within last 12 months y/n
One or more blood pressure measurements within last 12 moths y/n
Hypertension prevalent within last 12 months y/n
Received antihypertensive medication within last 12 months
Diabetes specific education at least once before
Treatment with diet only
Treatment with sulfonylurea y/n within last 12 months
Treatment with biguanides y/n within last 12 months
Treatment with glucosidase inhibitors y/n within last 12 months
Treatment with glitzones y/n within last 12 months
Treatment with glinides y/n within last 12 months
Treatment with insulin within last 12 months
Pump therapy within last 12 months y/n
Average number of insulin injections per day
Self monitoring of blood/urine glucose within last 12 months
Clinically diagnosed CVD
Treatment with anti-platelet therapy within last 12 months
Treatment with lipid lowering medication within last 12 months

Outcome - intermediate outcomes

Most recent HbA1c level (number)
Most recent Total Cholesterol
Most recent HDL Cholesterol
Most recent systolic blood pressure
Most recent diastrolic blood pressure

Most recent Weight

Most recent BMI (Calculated from Weight, Height)
Retinopathy prevalent within last 12 months

Maculopathy prevalent within last 12 months
Fundus inspection within last 12 months
Eye laser treatment ever
Positive testing for urinary albumin within last 12 months (Y/N/null)
Smoking currently y/n
Current alcohol abuse/dependence y/n
Former or current foot ulceration

Outcome - terminal outcomes

Blindness prevalent Blindness newly diagnosed within last 12 months
Dialaysis and/or transplantation new within last 12 months
ESRD prevalent

History of amputation above ankle

Amputation above ankle new within last 12 months

History of stroke

Stroke new within last 12 months

History of myocardial infarction

Myocardial infarction new within last 12 months
Death within last 12 months