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

June 2006

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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 provider-level measures 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" 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?

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

[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

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?

The next step of the working process will be that all partners are invited to give feedback and to make additions and corrections to this proposal.
In sections 5.1 and 5.2 tables are given, where all partners can make comments and rate indicators.
All partner contributions will be collected and used as input for the first deliverable of this work package and as basis for discussion in the Malta meeting.

Sources used

Health indicators

- EUDIP ✓
- ECHI ✓
- OECD ✓

Guidelines

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

3. Data Items

3.1 Risk profile for Diabetes

3.1.1 Obesity

Parameter

BMI (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
- 18. De Vegt F, Dekker JM, Jager A, Hienkens E, Kostense PJ, Stehouwer CD, Nijpels G, Bouter LM, Heine RJ (2001) Relation of impaired fasting and post load glucose with incident type 2 diabetes in a Dutch population: the Hoorn study . JAMA 285 : 2109-2113.
- 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.

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.

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)

Has not been discussed further by the EUDIP group.

EUROHIS: questions on nutritional habits included

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

3.3 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

- 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
- Davis TME, Millns H, Stratton IM, et al. Risk Factors for Stroke in Type 2 Diabetes Mellitus. United Kingdom Prospective Diabetes Study (UKPDS) 29. Arch Intern Med 1999;159:1097-103
- 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
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)

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)

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:

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

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

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

LDL-Cholesterol: Value in mg/dl (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. We recommend including triglycerides together with an item for fasting status.

Discussion: Graham Leese: 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.

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

Sven Skeie: True- fasting status often unavailable but I think TG still should be included.

Peter Beck: FQSD has a data item for fasting (y/n) – In Austria people come to clinic fasted

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

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
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Comment

Sven Skeie: No 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.

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

3.3.7 Alcohol

Parameters

Average intake (grams/week)

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

Presence of alcohol abuse/dependence

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*)

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tolerance: the Paris Prospective Study after 15 years of follow-up. J Clin Epidemiol 44 (6) (1991) 465-474.

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- 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:

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.

Additional transformation 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

Parameter

Presence of drug abuse

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.

3.3.9 Foot Screening

Parameters

Former 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

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- 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

References

IDF

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EUDIP

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Comment

Graham Leese: You may want to consider recording modality ie ophthalmoscope, retinal photograph, slit lamp etc, if it doesn't make the data collection too complex.

Sven Skeie: Too complex I think

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].

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

Oral Therapy

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- 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
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- 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

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 (suggestion Graham Leese)
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
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- 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

Graham Leese: Need to add “animal insulin” to human and analogues. Some patients still use pork insulin by preference.
Sven Skeie: I think this is unnecessary, few patients and even fewer to come (in all countries?)

3.4.4 Blood pressure control

Parameters

Diuretics (Thiazide diuretics or spironolactone)
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
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- 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…

Fibrates

Ezetimibe (suggested by Graham Leese)

Nicotinic acid derivates (suggested by Graham Leese)

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
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and without the metabolic syndrome: subgroup analyses of the Scandinavian Simvastatin Survival Study (4S). Diabetes Care. 2004 Jul;27(7):1735-40.

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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)

Parameters

Coronary revascularization: PTA, anti-platelet therapy

References

SIGN 32

Coronary revascularization

SIGN 55

Thrombolytic therapy

Comment

Coronary revascularization

CABG: better outcome than PTCA

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:

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- 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.
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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.
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- 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

→ see 3.1.2 (HEPA)

References

Canada:

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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).

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…)
Diabetic patient organisation (membership, contact with)
Target Agreements (HbA1c, blood pressure, physical activity, diet, smoking, alcohol, …)

References

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IDF

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Comment

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

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IDF

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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
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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.

3.6 Complications

3.6.1 Acute Complications

Hypoglycaemia
Hyperglycaemia/Ketoacidosis/Lactic acidosis

3.6.2 Eye complications

Parameters

Blindness
Retinopathy, proliferative and mild, severe non proliferative
Photocoagulation
Maculopathy (diabetes related)
Severe vision loss
Partial sightedness

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.,
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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)

Vision (in%) (0 – 120 or empty)

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

Creatinine level

Nephropathy incipient/ manifest

ESRD (end stage renal disease = ESRF end stage renal failure)

Type of renal replacement therapy

Glomerular filtration rate (GFR)

Albumin-creatinine ratio

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

References

EUDIP:

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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.

Comments

= Microvascular complication

Graham Leese: ESRF. This needs careful defining. Options may include:

a) Creatinine over 400µmol/l (as in EUDIP) (or use cut-off 150µmol/l?) or previous renal transplant
b) On dialysis or transplantation
c) Others

As different centres start patients on dialysis at different times, Id suggest something like the first definition. This definition is more objective.

Sven Skeie: Outcome indicator creatinine>400? – This seems too high.

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

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

US Guideline:

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

Pharmacologic therapy on foot disease

Number of patients admitted to hospital with foot related problems (Suggestion Graham Leese)

EUDIP indicators

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

References

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SIGN 55:

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IDF:

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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

Healed ulcer

Acute ulcer

3.6.5 Neuropathy

Parameters

Neuropathy

- Sensory neuropathy (numb feet etc.)
- Painful sensory neuropathy
- Autonomic neuropathy

Sexual dysfunction

References

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IDF:

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Comment

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

Angina pectoris

Stroke / Apoplexy

CHD (coronary heart disease) - risk

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

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.
- 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

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

More see 3.6.4, Foot complications

References

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.

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, white collar/blue collar worker/education/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
Life expectancy & 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)

General mortality

Numerator: Annual death rate in the general population from all causes/100,000 general population, adjusted for European Standard Population
Denominator: general mortality per age group

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

NZ Guidelines

- 346. Hay D, Cardiovascular disease in New Zealand, 2001: A summary of recent statisitical information. 2002, The National Heart Foundation of New Zealand: Auckland.

Comments

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), nurses, pharmacies, ophthalmologists…

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

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:

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

3.8.2 Health care expenditures/financing [2]

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

[2] 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.

Total health expenditure by age group
Health expenditure by fund source

References

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

Comments

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

References

EUDIP Group 2002
Establishing indicators monitoring diabetes mellitus and its morbidity

3.10 FQSD/Diabcare Checkup

3.10.1 Items not yet considered

DiabCare

- 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) → discuss
- Number of sick days
- Number of inpatient days

4. Indicators

4.1 Epidemiology

4.1.1 Indicators and definition

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

Required Items

Annual number of (standardised) new diagnoses (see: Diagnosis and classification) of type 1 diabetes, total number of children between 0-14 yrs

Source

EUDIP

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

Required Items

Annual number of (standardised) new diagnoses (see: Diagnosis and classification) of type 1 diabetes

Source

Suggestion Joanneum

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

Required Items

Annual number of (standardised) new diagnoses (see: Diagnosis and classification) of type 2 diabetes

Source

Suggestion Joanneum

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

Required Items

Annual number of (standardised) new diagnoses (see: Diagnosis and classification)

Total number of general population in the study region/country

Source

EUDIP

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

Required Items

Annual number of (standardised) new diagnoses (see: Diagnosis and classification) of type 1 and type 2 diabetes.

Source

Suggestion Joanneum

Prevalence of persons with impaired glucose tolerance and/or diet only

Numerator: Number of persons at a given time with impaired glucose tolerance and/or diet only

Denominator: Total number of general population in the study region/country/1,000

Required Items

Diagnoses (see: Diagnosis and classification)

Source

EUDIP

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

Required Items

See: Eye complications

Blindness new within last 12 months

Cause of blindness

Newly diagnosed cases of blindness in general population within a given time

Source

EUDIP “Retinopathy”

Percent with ESRF in last 12 months in total population

Numerator: Number of ESRF within the last 12 months

Clear definition of ESRF:

a.) Creatinine over 400 μmol/l or previous renal transplant

b.) On dialysis or transplant

c.) Others

Denominator: Total number of general population in the study region/country

Required Items

Annual number of ESRF in last 12 months (see: Diagnosis and classification)

Source

EUDIP “Nephropathy”

EUDIP Comment

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.

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 general population in the study region/country/1,000,000

Required Items

See: Kidney damage/Nephropathy

Source

EUDIP

Prevalence (stock) 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 general population in the study region/country/1,000,000

Required Items

See: Kidney damage/Nephropathy

Source

EUDIP

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 general population in the study region/country/100,000

Required Items

Annual number of non-traumatic (medical) amputations (see: Foot complications)

Source

EUDIP – “Vascular Disease”

EUDIP Comment

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.

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 general population in the study region/country/100,000

Required Items

Annual number of non-traumatic (medical) amputations (see: Foot complications)

Source

Suggestion Joanneum

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 general population in the study region/country/100,000

Required Items

Annual number of new stroke events, see: Cardiovascular disease (CVD)

Source

EUDIP

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 general population in the study region/country/100,000

Required Items

Annual number (stock) of strokes, see: Cardiovascular disease (CVD)

Source

Suggestion Joanneum

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 general population in the study region/country/100,000

Required Items

Annual number of new myocardial infarctions, see: Cardiovascular disease (CVD)

Source

EUDIP

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 general population in the study region/country/100,000

Required Items

Annual number (stock) of myocardial infarction, see: Cardiovascular disease (CVD)

Source

Suggestion Joanneum

4.1.2 References

EUDIP

Incidence Type 1 (0-14):

30. 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

31. 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

4.1.3 Comment

EUDIP:

- Incidence Type 1 (0 – 14): 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).
  Assessment of incidence for all type 1 patients?

- All indicators given in percent instead of 100,000 etc.?
- Should ESRF be separated from dialysis and transplantation?
- Assessment of impaired glucose tolerance possible?

4.2 Structural quality

4.2.1 Indicators and definition

Hospital beds per 100,000 population

Numerator: Number of hospital beds

Denominator: Population in the study region/country/100,000

Required Items

See: Health care resources & delivery of care

Source

ECHI

Physicians employed per 100,000 population

Numerator: Number of physicians

Denominator: Population in the study region/country/100,000

Required Items

See Health care resources & delivery of care

Source

ECHI

Number of diabetologists per 100,000

Numerator: Number of diabetologists

Denominator: Population in the study region/country/100,000

Required Items

See Health care resources & delivery of care

Source

Suggestion Joanneum

Comments

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 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

Required Items

See Health care resources & delivery of care

Source

Suggestion BIRO plenary meeting in Malta

Nurses employed per 100,000

Numerator: Number of diabetes specific nurses

Denominator: Population in the study region/country /100,000

Required Items

See Health care resources & delivery of care

Source

ECHI

Number of diabetes nurses employed per 100,000

Numerator: Number of diabetes specific nurses

Denominator: Total number of inhabitants in the study region/country/100,000

Required Items

See Health care resources & delivery of care

Source

Suggestion Joanneum

Number of structured Disease Management Programmes

Numerator: Number of DMPs available in region

Denominator: One

Required Items

Disease Management Program (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

Source

Suggestion Joanneum

Comment

Disease Management Programmes in best-case scenarios are based on scientifically proven results.

Health care expenses per inhabitant

Numerator: Health care expenses

Denominator: Population in the study region/country

Required Items

Health expenses see: Health care expenditures/financing , number of inhabitants

Source

Suggestion Joanneum

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

Required Items

See: Diagnosis of Diabetes

Age at diagnosis

Source

EUDIP – “Risk factors for complication”

EUDIP Comment

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.

Average age at diagnosis of diabetes per country

Numerator: Sum of ages of patients at diagnosis
Denominator: Total number of diabetic patients in the study region/country
Required Items
See: Diagnosis of Diabetes
Source
Suggestion Joanneum

4.2.2 References

ECHI-2

4.2.3 Comment

Educational level and number of outpatient treatments need to be assessed.

4.3 Process quality

4.3.1 Indicators and definition

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
Required Items
Number of HbA1c tests (see: Glucose level) in diabetic patients, number of all patients diagnosed with diabetes.
Source
OECD

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

Required Items

Number of Total cholesterol/HDL tests (see: Lipids) in diabetic patients, number of all patients diagnosed with diabetes.

Source

EUDIP, OECD, modified

Comments

EUDIP uses lipid profile, OECD uses LDL only.

In BIRO we recommend Total cholesterol/HDL tests, so we count them in this process indicator.

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

Required Items

Test for microalbuminuria (Microalbuminuria (Urinary Albumin)), medical attention for existing nephropathy (Kidney damage/Nephropathy), number of all patients diagnoses with diabetes

Source

OECD

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

Required Items

Eye examination, retinal photography by an ophthalmologist or optometrist (Eye screening), number of diabetic patients

Source

OECD, modified by the BIRO group

Discussion

The OECD version of this indicator is “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”

The time measures were modified to “within the last 12 months” 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.

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
Required Items
See: Foot Screening
Number of diabetic patients
Source
OECD

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
Required Items
Smoking status (see: Smoking)
Source
OECD

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
Required Items
See: Alcohol
Source
Suggestion Joanneum

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
Required Items
See:
Source
EUDIP

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

Required Items

See: Blood pressure control

Source

EUDIP

Percentage of patients with hypertension who receive antihypertensive medication

Numerator: Number of diabetes patients with hypertension who receive antihypertensive medication

Denominator: Number of clinically diagnosed diabetes patients with hypertension in the study region/country

Required Items

See: Blood pressure control

Source

Suggestion Joanneum

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

Required Items

See: Psychological care: Screening for depression

Source

Suggestion Joanneum

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

Required Items

See: HRQoL

Source

Suggestion Joanneum

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

Required Items

See:

Source

Suggestion Joanneum

Thrombolytic therapy in diabetic patients with myocardial infarction

Numerator: Number of diabetes patients with thrombolytic therapy in patients with myocardial infarction

Denominator: Number of clinically diagnosed diabetes patients with coronary heart disease in the study region/country

Required Items

See:

Source

Suggestion Joanneum

Type of oral therapy (distribution of agents) in patients with diabetes type 2

Numerator: Number of diabetes patients with biguanides, sulfonuria etc.

Denominator: Number of clinically diagnosed diabetes patients in the study region/country who receive oral therapy

Required Items

See: Glucose control: Oral therapy

Source

Suggestion Joanneum

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

Required Items

See: Glucose control: Insulin therapy

Source

Suggestion Joanneum

Portion of patients teated 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

Required Items

See: Glucose control: Insulin therapy

Source

Suggestion Joanneum

Type of insulin therapy

Numerator: Number of diabetes patients receiving insulin as CIT, MDI, ODI, PIT

Denominator: Number of clinically diagnosed diabetes patients in the study region/country who receive insulin therapy

Required Items

See: Glucose control: Insulin therapy

Source

Suggestion Joanneum

Comments

This indicator was dropped in the BIRO meeting in Malta because the names of the terms for the insulin therapy types do not cover various therapy mixes

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

Required Items

See: Glucose control: Insulin therapy

Source

BIRO meeting Malta

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

Required Items

See: Glucose control: Insulin therapy

Source

BIRO meeting Malta

Comments

To be further discussed: Computing the average doesn't give any information on therapy types used. Maybe an analysis of distribution of insulin injections can help guessing…

Portion of diabetic patients treated with diet only

Numerator: Number of patients with diabetes receiving diet only

Denominator: Number of clinically diagnosed diabetes patients in the study region/country

Required Items

See: Diet

Source

Suggestion Joanneum

Type of blood pressure measurement

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

Eligible methods for blood pressure measurement are: physician/home measurement, 24 hour measurement.

Required Items

See: Blood pressure control

Source

Suggestion Joanneum

Comment

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

Type of blood pressure treatment in patients with diabetes

Numerator: Number of diabetes patients with hypertension separated according to type of antihypertensive medication

Denominator: Number of clinically diagnosed diabetes patients with hypertension in the study region/country

Required Items

See: Blood pressure control

Source

Suggestion Joanneum

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

Required Items

See: Blood pressure control

Source

Suggestion Joanneum

Average number of antihypertensive agents used per diabetes patient with anti hypertensive treatment

Numerator: Sum number of antihypertensive agents used per diabetes patient (only patients with anti hypertensive treatment included)

Denominator: Number of patients with anti hypertensive treatment

Required Items

See: Blood pressure control

Source

Suggestion Sven Skeie

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

Required Items

See: Education/Empowerment

Source

Suggestion Joanneum

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

Required Items

See: Self monitoring and life style interventions

Source

Suggestion Joanneum

Percentage of depressive patients treated during last 12 months

Numerator: Number of diabetes patients who got depression treatment during the last 12 months

Denominator: Number of diabetes patients with diagnosed depression during the last 12 months

Required Items

Depression, depression treatment

Source

Suggestion Joanneum

4.3.2 References

OECD

- 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.

4.3.3 Comment

OECD:

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).

4.4 Outcome quality – intermediate outcomes

4.4.1 Indicators and definition

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

Required Items

See:

Glucose level

Source

OECD

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

Required Items

See:

Glucose level

Source

OECD

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

Required Items

See: Lipids

Source

Suggestion Joanneum

Comments

Graham Leese: Percentage of patients with LDL-cholesterol

Since very few patients have LDL measured directly, and many patients have non-fasting (or unknown) triglycerides which invalidates the calculation of LDL-cholesterol I suspect we shall have very little reliable data on LDL-cholesterol. I thus wonder if we should stick to Total cholesterol and HDL-cholesterol measurements (see arguments above on lipids).

→ Use Total cholesterol/HDL instead of LDL

Sven Skeie: Yes – LDL can not be used without running into interpretation problems and missing data. Ratio total-chol/HDL is a good option.

Graham Leese: For reasons mentioned above, I wonder if we should use a total cholesterol cut off of 4 or 5 mmol/l, and not an LDL-cholesterol cut off.

Sven Skeie: LDL is not a good outcome indicator. Standardized unit should be used (mmol/L)

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

Required Items

Total cholesterol

HDL cholesterol

See: Lipids

Source

Suggestion Dundee

Comments

Adopted after discussion in BIRO Malta meeting 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

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

Required Items

See: Blood pressure

Source

OECD

Discussion

Suggestion Graham Leese: Record percentage of patients with SBP >140 separately from percentage patients with DBP >90

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

Required Items

See: Psychological care: Screening for depression

Source

Suggestion Joanneum

Percentage of patients with BMI ≥ 30 kg/m^2

Numerator: Number of patients with BMI $\geq$ 30

Denominator: Number of clinically diagnosed diabetes patients in the study region/country

Required Items

See: Weight

Source

EUDIP

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

Required Items

Waist circumference, ethnicity

Comment

It might be hard to collect ethnicity

Source

Suggestion Dundee, adopted in BIRO meeting in Malta

Percentage of persons with diabetes mellitus with a fundus inspection in the last 12 m, who have proliferate retinopathy and/or maculopathy

Numerator: Number of persons with diabetes mellitus with fundus inspection in the last 12 months and proliferate retinopathy

Denominator: Number of clinically diagnosed diabetes patients in the study region/country

Required Items

See: Eye screening, Eye complications

Comment

EUDIP called it … who has proliferate retinopathy

Source

EUDIP

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: Number of clinically diagnosed diabetes patients in the study region/country

Required Items

See: Eye screening, missing

Source

EUDIP

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

Required Items

See: Eye complications

Source

Suggestion Joanneum

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

Required Items

See: Smoking

Source

EUDIP

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

Required Items

Test for urinary albumin (y/n)

Urinary albumin test result (positive/negative)

Source

BIRO meeting Malta

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

Required Items

See: Alcohol

Source

Suggestion Joanneum

Rate of patients with current drug abuse

Numerator: number of patients with current (illegal) drug abuse among diabetes patients

Denominator: Number of clinically diagnosed diabetes patients in the study region/country

Required Items

Source

Suggestion Joanneum

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

Required Items

Number of patients with former or acute ulceration (see: Foot complications)

Source

Suggestion Joanneum

4.4.2 References

OECD:

- 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.

4.4.3 Comments

OECD:

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).

4.5 Outcome Quality – Terminal outcomes

4.5.1 Indicators and definition

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

Required Items

See:

Cardiovascular deaths, classification of death: Population and Socio-economic factors

Source

OECD – newly proposed measures

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

Source

EUDIP, modified in the BIRO meeting in Malta

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 to record the reason for blindness

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

Required Items

See: Eye complications

Source

Suggestion Joanneum - Retinopathy

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

Required Items

See: Kidney damage/Nephropathy

Source

Suggestion Joanneum

ESRD in Persons with Diabetes

Numerator: Number of diabetes patients with ESRD

Denominator: Number of clinically diagnosed diabetes patients in the study region/country

Required Items

Number of ESRD (Kidney damage/Nephropathy)

Source

OECD

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

Required Items

See: Peripheral vascular disease (PVD), Foot complications

Source

OECD, EUDIP

Comments

The EUDIP definition was preferred compared to the OECD definition “amputations above or below knee”

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

Required Items

See: Cardiovascular disease (CVD)

Source

Suggestion Joanneum

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

Required Items

See: Cardiovascular disease (CVD)

Source

Suggestion Joanneum

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

Required Items

See: Cardiovascular disease (CVD)

Source

Suggestion Joanneum

Prevalence of myocardial infarction in patients with diabetes

Numerator: Number of stroke in patients with myocardial infarction

Denominator: Number of clinically diagnosed diabetes patients in the study region/country

Required Items

See: Cardiovascular disease (CVD)

Source

Suggestion Joanneum

Annual death rate per 100,000 populations in the general population from all causes, adjusted for standard European population

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 from all causes, adjusted for standard European population and the Annual death in patients, who have as primary or secondary cause of death, diabetes mellitus, adjusted for standard European population.

Denominator: General population/100,000

Required Items

See: Population and Socio-economic factors

Source

EUDIP

Comments

To be further discussed:

→ Talk to Fred Storms/EUCID

→ Use “Mortality rate in diabetic population” instead?

Risk for mortality attributable to diabetes mellitus

Numerator: Diabetes specific mortality per age group

Denominator: General mortality per age group

Required Items

See: Cause for mortality: Population and Socio-economic factors

Source

Suggestion Joanneum

4.5.2 References

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.

4.5.3 Comment

Incidence parameters should be evaluated additionally

5. Short list

The indicators marked with ✓ were selected in the BIRO meeting in Malta as core indicator candidates.

5.1 Indicators

		Comment **Score**: YES/NO	Source	Importance	Feasibility	Scientific Soundness	Test/discuss
	Epidemiology[3]						
1 ✓	Annual Incidence of Type 1 Diabetes in children between 0-14 years of age at diagnosis (clinical) per 100,000 children	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 (%)	It is based on the EUDIP indicator [1] enclosing all age groups. - Diagnosis more difficult in adults.	Joanneum	Y	Y	Y	
3	Annual incidence of Type 2 Diabetes (%)	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.	Joanneum	Y	?	Y	
4 ✓	Prevalence of diabetes mellitus per 1,000	No distinction between type 1 and type 2 diabetes. + Often this information comes from prescription data → no diabetes type given → better feasibility	EUDIP Core	Y	Y	?	
5	Prevalence of diabetes mellitus (type 1 and type 2, respectively) (%)	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…)	Joanneum	Y	?	Y	
6	Prevalence of persons with impaired glucose tolerance	- 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	+ blindness is major diabetes outcome - requires measurement of total annual incidence of blindness and blindness due to diabetic retinopathy → too hard to assess	EUDIP Core	Y	N	Y	
8	Percent with ESRF in last 12 months in total population	- Relevance: Relation to total population mainly interesting for epidemiologists.	EUDIP	Y	Y	Y	

[3]These indicators are related to the general population. Similar indicators, relating to diabetic population, can be found in the outcome quality section.

		Score: YES/NO **Comment**	**Source**	Importance	Feasibility	Scientific Soundness	Test/discuss
		Data on this issue is available in national registries. Reimbursement systems may offer information since both of them are coded according to the ICD.	second				
9	Annual incidence of dialysis and/or transplantation (renal replacement therapy in patients with diabetes)/general population	- 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 (stock) of dialysis/transplantation (renal replacement therapy) in patients with diabetes/general population	- 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	- Relevance: Relation to total population mainly interesting for epidemiologists. Data source should be the surgical act, surgical records.	EUDIP	Y	?	Y	
12	Prevalence of non-traumatic (medical) amputations, above the ankle in persons with diabetes/general population	- Relevance: Relation to total population mainly interesting for epidemiologists. This indicator complements indicator [11].	Joanneum	?	N	Y	
13	Annual incidence of stroke in patients with diabetes/general population	- 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	- Relevance: Relation to total population mainly interesting for epidemiologists. This indicator supplements [13].	Joanneum	?	?	Y	
15	Annual Incidence of myocardial infarction in patients with diabetes/general population	- 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	- Relevance: Relation to total population mainly interesting for epidemiologists. Modification of indicator [15].	Joanneum	?	?	Y	
17 ✓	Age at diagnosis by 10 year age bands (incidence)	Source: Patient records, DiabCare One often has to rely on information given by the patient.	EUDIP second	?	Y	Y	
18	Average age at diagnosis of diabetes per country	Modification of indicator [17].	Joanneum	?	Y	?	
	Structural quality						
19 ✓	Hospital beds per 100,000 population	Not all categories of beds have to be collected separately, maybe just count hospital beds.	ECHI-2	?	Y	Y	
20 ✓	Physicians employed per 100,000 population	This indicator might be easy to assess. National statistics can provide information on this indicator.	ECHI-2	Y	Y	Y	
21 ✓	Number of diabetologists per 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.	Joanneum	Y	?	Y	
22 ✓	Number of doctors who regularly take care of diabetic patients in diabetes clinics in primary or secondary care per 100,000	Definition “regularly” to be discussed	BIRO meeting Malta				

		Score: YES/NO **Comment**	**Source**	Importance	Feasibility	Scientific Soundness	Test/discuss
23	Nurses employed per 100,000	Data available from national statistics	ECHI-2	Y	Y	Y	
24 ✓	Number of diabetes nurses employed per 100,000	Introduced to distinguish between nurses and specialized diabetes nurses.	Joanneum	Y	?	Y	
25 ✓	Number of structured Disease Management Programmes	Availability of a DMP influences the level of structured and evidence based treatment.	Joanneum	Y	Y	Y	
26	Health care expenses per inhabitant	It is common use to compare health care systems by the amount of health care expenses. National statistics provide information on this indicator.	Joanneum	Y	Y	Y	
	Process quality						
27 ✓	Percentage of patients with one or more HbA1c tests during the last 12 months	+ 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	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	Y	Y	Y	
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	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	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	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	See description indicator [27].	OECD	?	Y	Y	
33	Percentage of patients whose alcohol use was ascertained and documented within the last 12 months	This indicator displays the above-mentioned indicator [32] modified for alcohol use.	Joanneum	?	Y	?	
34 ✓	Percent with serum creatinine tested in last 12 months		EUDIP second	Y	Y	Y	
35 ✓	Percentage of patients with diabetes and one or more blood pressure measurements within the last 12 months	Very important process!	EUDIP second	Y	Y	Y	
36 ✓	Percentage of patients with hypertension who receive antihypertensive medication	Hypertension is defined by either hypertension treatment or blood pressure > 140/90	Joanneum	Y	?	Y	
37	Percentage of patients with one or more depression tests annually	Recent guidelines emphasize the importance of screening for depression. Excluded in BIRO Meeting in Malta,	Joanneum	Y	Y	Y	

		Score: YES/NO Comment	Source	Importance	Feasibility	Scientific Soundness	Test/discuss
		please rediscuss this, the evidence is given					
38 ✓	Percentage of patients with diabetes specific education at least once before	Diabetic specific education can lead to better outcome in patients with diabetes.	Joanneum	Y	?	Y	
39	Thrombolytic therapy in diabetic patients with myocardial infarction	- Feasible?	Joanneum	Y	N	Y	
40 ✓	Type of oral therapy (distribution of agents) in patients with diabetes type 2	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”	Joanneum	?	Y	?	
41 ✓	Portion of patients treated with insulin among patients with diabetes	Relevant for type 2.	Joanneum	Y	Y	?	
42 ✓	Portion of patients teated with insulin in combination with OADs among patients with diabetes	Relevant for type 2.	Joanneum	Y	Y	?	
43	Type of insulin therapy	CSII, MDI, ODI, PIT This indicator was dropped in the BIRO meeting in Malta (see indicator description)	Joanneum	Y	Y	Y	
44 ✓	Percentage of insulin treated patients with pump therapy	This indicator is a subset of indicator [43]	BIRO meeting Malta	Y	Y	Y	
45 ✓	Average number of insulin injections per day in insulin treated patients	This indicator was introduced in the BIRO meeting in Malta because of the problems with indicator [43] Further discussion required, see indicator description!	BIRO meeting Malta	?	Y	?	
46	Portion of diabetic patients treated with diet only	Item is present in DiabCare data set	Joanneum	Y	?	?	
47	Type of blood pressure measurement	EUDIP suggested the standardization of blood pressure measurement. The method might be documented in the patient’s record. Not considered relevant in BIRO meeting in Malta	Joanneum	N	N	Y	N
48	Type of blood pressure treatment in patients with diabetes	Which anti hypertensive agents are used? Interesting for treatment processes, maybe even for research? But hard to record → not feasible	Joanneum	Y	N	?	
49 ✓	Portion of diabetes patients with anti hypertensive treatment	Included instead of indicator [48] in BIRO meeting in Malta	Joanneum	Y	Y	Y	
50	Average number of antihypertensive agents used per diabetes patient with anti hypertensive treatment	Feasibility not clear, number of antihypertensive agents not regularly recorded	Bergen	Y	?	?	
51 ✓	Percent of patients with diabetes performing self-monitoring of blood glucose/ urine testing	Important process for patient empowerment	Joanneum	?	Y	Y	

		Score: YES/NO Comment	Source	Importance	Feasibility	Scientific Soundness	Test/discuss
52	Percent of patients with hypertension performing self-monitoring of blood pressure	Important process for patient empowerment Excluded in BIRO meeting in Malta. Rediscuss this, evidence is there	Joanneum	Y	Y	Y	
53	Percentage of depressive patients treated during last 12 months	Depression needs to be not only recorded but also addressed in practice	Joanneum	Y	?	Y	
	Outcome quality – intermediate outcomes						
54 ✓	Percentage of patients with most recent HbA1c level >9.0% (poor control)	Use OECD indicator definition for international comparability. + Important parameter	OECD +EUDIP second	Y	Y	Y	
55 ✓	Percentage of patients with most recent HbA1c level >7,5%	Modification of indicator [54] 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	
56	Percentage of patient with most recent LDL<130 mg/dl	See description indicator [54] 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	
57 ✓	Percentage of patients with Total-Chol / HDL-Chol < 4.5	Selected instead of indicator 56 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	
58 ✓	Percentage of patients with most recent blood pressure <140/90 mmHg	See description indicator [54] Some guidelines use lower threshold value – for outcome quality measurement 140/90 is appropriate. → show distribution in addition	OECD	Y	Y	Y	
59	Percentage of patients with depression (Wellbeing 5 level below 13)	See description indicator [37].	Joanneum	Y	Y	Y	
60 ✓	Percentage of patients with BMI ≥ 30	Overweight and obesity are considered as a major risk factor for developing micro and macro vascular complications. Overweight is defined as BMI ≥ 25 kg/m^2 Obesity is defined as BMI ≥ 30 kg/m^2	EUDIP second	Y	Y	Y	
61 ✓	Percentage of patients with waist circumference above IDF cut-offs	94cm (men) and 80cm (women) for europids and 90 and 80cm for S. Asians and Chinese, and 85cm (men) and 90 (women) for Japanese)	Dundee, BIRO meeting Malta	Y	Y	Y	
62 ✓	Percentage of persons with diabetes mellitus with a fundus inspection in the last 12 m, who have proliferate retinopathy and/or maculopathy	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-	EUDIP second	Y	Y	Y	

		Score: YES/NO **Comment**	**Source**	Importance	Feasibility	Scientific Soundness	Test/discuss
		Codes a validation of laser treatment is possible.					
63	Percent who received laser treatment <3 months after diagnosis of proliferative retinopathy	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	
64 ✓	Percentage of patients with eye laser treatment ever	Intermediate outcome for retinopathy Interesting to compare how health care systems deal with retinopathy	Joanneum	Y	Y	Y	
65 ✓	Percentage with microalbuminuria in last 12 months (among those who have been tested)	that gives a rate of "newly found" patients with microalbuminuria - Difficult to compare (who has been screened??)	EUDIP second				
66 ✓	Rate of current smokers among diabetes patients	Smoking is an important risk factor.	EUDIP second	Y	Y	Y	
67 ✓	Rate of patients with current alcohol abuse/dependence		BIRO meeting Malta	Y	?	Y	
68	Rate of patients with current drug abuse	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	Y	Y
69 ✓	Former or current foot ulceration	"Foot on Risk…"	Joanneum	Y	Y	Y	
	Outcome Quality – Terminal outcomes						
70	Cardiovascular mortality in patients with diabetes	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	OECD	Y	N	Y	
71 ✓	Annual incidence of blindness in patients with diabetes (among those visited during the last 12 months)	+ Easier to assess than indicator [7] + incidence of blindness is St. Vincent target - "due to diabetic retinopathy" is hard to assess	Joanneum	Y	?	Y	
72	Prevalence of blindness due to diabetic retinopathy in diabetic patients	+ Easier to assess than indicator [7] The same modification as for indicator [71] is recommended. Excluded from BIRO set of indicators because prevalence is too hard to assess.	Joanneum	Y	N	Y	
73 ✓	Annual incidence of dialysis and/or transplantation (renal replacement therapy in patients with diabetes	This indicator modifies indicator [9] to be used as outcome indicator.	Joanneum (EUDIP)	Y	Y	Y	
74 ✓	ESRD in Persons with Diabetes	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	
75	Annual incidence of amputations above the ankle	major (above or below knee) amputations	EUDIP	Y	?	Y	

		Score: YES/NO Comment	Source	Importance	Feasibility	Scientific Soundness	Test/discuss
✓		OECD suggestion is “Lower extremity amputation rates”. EUDIP uses a definition “amputations above the ankle” in indicator [11]	OECD				
76 ✓	Annual incidence of stroke in patients with diabetes	This indicator modifies indicator [13] to be used as outcome indicator. - stroke and diabetes have to be known in combination	Joanneum (EUDIP)	Y	?	Y	
77	Prevalence of stroke among diabetes patients	This indicator supplements indicator [76]	Joanneum	Y	N	Y	
78 ✓	Annual Incidence of myocardial infarction in patients with diabetes	This indicator modifies indicator [15] to be used as outcome indicator. - stroke and diabetes have to be known in combination	Joanneum (EUDIP)	Y	?	Y	
79	Prevalence of myocardial infarction in patients with diabetes	Supplement to indicator [78].	Joanneum	Y	N	Y	
80 ✓	Annual death rate per 100,000 populations in the general population from all causes, adjusted for standard European population 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.	Major indicator for diabetes complications. EUDIP suggests the linkage of the death rate with gender and age. Data sources are national registries. - diabetes usually is not recorded as primary or secondary cause of death Further discussion required, see indicator description	EUDIP Core	Y	N	Y	
81	Risk for mortality attributable to diabetes mellitus	- Requires diabetes specific mortality and mortality in general population per age group.	Joanneum	Y	?	Y	

Suggestions for further indicators

Overweight/Obesity: BMI % of general population _>25 and_> 30kg/m^2 (EUDIP core indicator, but out of scope for BIRO?)

Indicator for nutritional habits (HIS questions) → Come up with a suggestion, but no data to use it in the moment

Indicator for Physical activity (IPAQ questions) → Come up with a suggestion, but no data to use it in the moment

5.2 Data Items

5.2.1 Data Items required per indicator

Data Item	Required for Indicator
Epidemiology	
Diabetes type	1
Year of diagnosis	1,4
Total number of children between 0-14 yrs	1
Diabetes y/n	4, all process indicators, all outcome indicators except 65
Total number of general population in area	4,19,20,21,22,23,24,25
Age at diagnosis	17
Structural quality	
hospital beds in area	19
physicians employed in area	20
number of diabetologists in area	21
number of doctors who regularly take care of diabetic patients in diabetes clinics in primary or secondary care in area	22
nuber of diabetes nurses employed in area	24
number of structured disease mangement programmes in area	25
Process quality	
Number of clinically diagnosed diabetes patients in the area	All process indicators, all outcome indicators except 65
HbA1c tested within last 12 months y/n	27
Total Chol/HDL tested within last 12 months y/n	28
Microalbuminuria tested within last 12 months y/n	29
Medical attentien for nephropathy within last 12 months y/n	29
Dilated eye examination or evaluation of retinal photography by a trained caregiver within the last 12 months y/n	30
At least one foot examination within last 12 months y/n	31
Smoking status ascertained within last 12 months y/n	32
Serum creatinine tested within last 12 months y/n	34
One or more blood pressure measurements within last 12 moths y/n	35
Hypertension prevalent within last 12 months y/n	36
Received antihypertensive medication within last 12 months	36,49
Diabetes specific education at least once before	38
Treatment with (sulfonylurea y/n, biguanides y/n, glucosidase inhibitors y/n, glitzones y/n, glinides y/n) within last 12 months	40
Treatment exclusively with insulin within last 12 months	41,44,45
Treatment with insulin in combination with one or more OADs within last 12 months	42,44,45
Pump therapy within last 12 months y/n	44
Average number of insulin injections per day	45
Self monitoring of blood/urine glucose testing within last 12 months	51
Outcome - intermediate outcomes	
Most recent HbA1c level (number)	54,55
Most recent Total Chol/HDL Chol	57
Most recent blood pressure systolic/diastolic	58
Most recent BMI	60

Data Item	Required for Indicator
Most recent waist circumference	61
Sex	61
Ethnicity	61
Retinopathy prevalent within last 12 months	62
Maculopathy prevalent within last 12 months	62
Fundus inspection within last 12 months	62
Eye laser treatment ever	64
Positive testing for urinary albumin within last 12 months	65
Negative testing for urinary albumin within last 12 months	65
Smoking currently y/n	66
Current alcohol abuse/dependence y/n	67
Former or current foot ulceration	69
Outcome - terminal outcomes	
Blindness newly diagnosed new within last 12 months	71
Dialaysis/transplantation new within last 12 months	73
ESRD prevalent	74
Amputation above ankle new within last 12 months	75
Stroke new within last 12 months	76
Myocardial infarction new within last 12 months	78
Death within last 12 months	80